TRM 6100.02 INFECTIOUS DISEASE MANAGEMENT

U.S. Department of Justice
Federal Bureau of Prisons

Technical Reference

OPI: HSD
NUMBER: 6100.02
DATE: 1/26/99
SUBJECT: Infectious Disease Management

Infectious Disease Management

FEDERAL BUREAU OF PRISONS

INFECTIOUS DISEASE MANAGEMENT TECHNICAL REFERENCE MANUAL

REFERENCE MANUAL: Infectious Disease Management
Program Statement

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FEDERAL BUREAU OF PRISONS
TREATMENT GUIDELINES FOR VIRAL HEPATITIS

PURPOSE. The Federal Bureau of Prisons Treatment Guidelines for Viral Hepatitis provide recommended standards for the medical management of viral hepatitis for federal inmates.

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DEFINITIONS.

Hepatitis A is an acute viral hepatitis caused by a highly infectious RNA picornavirus that is transmitted primarily by the fecal-oral route. Hepatitis A has a mild to fulminant acute clinical presentation that does not progress to a chronic disease state.

HAV is hepatitis A virus.

HAV IgM is the antibody developed against HAV during acute infection. HAV IgM is present for 3-6 months after initial infection.

HAV IgG is the protective antibody developed against hepatitis A during convalescence. HAV IgG remains detectable for life and is indicative of remote infection with hepatitis A.

Hepatitis B is an acute or chronic viral hepatitis caused by a DNA virus transmitted perinatally, through blood exposure, and sexual contact. Hepatitis B has a self-limited to fulminant acute clinical presentation with approximately 10% of cases progressing to chronic hepatitis.

HBV is hepatitis B virus.

HBsAg is hepatitis B surface antigen, a viral envelope antigen that is detectable during acute or chronic hepatitis B infection and indicative of active, contagious disease.

HBV chronic carrier is a person infected with HBV with a positive serology for HBsAg for 6 months or greater.

HBc is hepatitis B core antigen, an immunogenic protein of the HBV core.

HBeAg is HBV e antigen, a secreted, viral antigen of the hepatitis B viral core that is indicative of active viral replication and increased infectiousness during acute or chronic HBV infection.

Anti-HBs is the antibody to hepatitis B surface antigen that develops during convalescence from hepatitis B. The presence of anti-HBs is indicative of remote infection with hepatitis B and usually indicates protection from recurrent or new infection with HBV.

Anti-HBc IgM is the antibody to hepatitis B core antigen that develops during the acute onset of hepatitis B, becoming undetectable 6-24 months after the onset of illness.

Anti-HBc (total) is the total antibody response to hepatitis B core antigen that develops during the onset of hepatitis B and remains detectable during convalescence. Measurement of anti-HBc is the preferred screen for remote HBV infection.

Anti-HBe is the antibody to hepatitis e antigen that develops as viral replication and active hepatitis B begin to wane. Development of anti-HBe coincides with the loss of HBe antigen.

Hepatitis C is an acute or chronic viral hepatitis caused by a RNA virus that is transmitted primarily by parenteral contact with blood.

HCV is hepatitis C virus.

Anti-HCV is the antibody to HCV core and nonstructural proteins that is detectable from several weeks to months after clinical hepatitis. The presence of anti-HCV is an indicator of HCV infection, not immunity.

Anti-HCV EIA is an enzyme immunoassay used to diagnose HCV infection by measuring antibodies to HCV antigens. The presence of anti-HCV by EIA in a person with risk factors for HCV infection strongly predicts HCV infection.

Anti-HCV RIBA is the recombinant immunoblot assay that measures antibodies to the HCV antigens used in EIA-2 through immunoblot technology. Measurement of antibodies to HCV by RIBA is used as a supplementary, "confirmatory," test for HCV infection, particularly for persons without risk factors for HCV infection who test positive for HCV antibodies by EIA.

HCV RNA assay is an assay used to qualitatively measure the presence of HCV RNA in serum. Qualitative measurement of HCV RNA is indicated prior to antiviral treatment of HCV infection.

HDV is hepatitis D (delta) virus, a defective RNA virus that requires HBsAg for structural integrity and replication.

Hepatitis D is an acute or chronic hepatitis caused by HDV that is transmitted primarily through injection drug usage, transfusion, or other parenteral exposures.

Delta coinfection is the simultaneous infection of HBV and HDV usually resulting in a clinical course similar to infection with HBV alone.

Delta superinfection is an acute infection of HDV with preexisting chronic HBV infection (HBsAg+), frequently exacerbating hepatitis B infection.

Anti-HDV IgM is the antibody to HDV that develops during acute delta

hepatitis and recurs or persists as a marker for chronic delta hepatitis.

Anti-HDV is the total antibody to HDV that develops following delta coinfection or superinfection. The presence of anti-HDV indicates previous infection with HDV, not necessarily active infection.

Clinician is a physician or mid-level provider.

Compensated cirrhosis is biopsy-proven cirrhosis of the liver without evidence of compromised liver synthetic function or other complications of cirrhosis.

Decompensated cirrhosis is biopsy-proven cirrhosis of the liver with evidence of compromised liver synthetic function or evidence of portal hypertension such as jaundice, variceal bleeding, encephalopathy, and ascites.

Enteric precautions are protective measures used to prevent the spread of infections transmitted by feces. Precautions include wearing gloves for handling infectious material, using gowns when soiling is likely, and discarding contaminated items as infectious waste. Masks are not required for enteric precautions.

PROCEDURES.

a. Hepatitis A

1. Diagnosis. Hepatitis A should be considered as a diagnosis for any inmate presenting with symptoms of acute hepatitis, e.g. jaundice, dark urine, and diarrhea. The mean incubation period of HAV infection until the onset of symptoms is 21 days (range: 15-45 days). Hepatitis A is an acute illness, that can rarely be fulminant and life threatening, but does not evolve to a chronic infection. Acute hepatitis A infection is confirmed by a positive serum HAV IgM that is detectable with the concurrent onset of clinical symptoms and elevation in liver enzymes. Unless evidence of previous hepatitis A infection exists (positive HAV IgG), all inmates presenting with acute hepatitis/diarrhea should be tested for the presence of HAV IgM. Routine screening for HAV infection in asymptomatic inmates is not clinically indicated or required for work assignments.

2. Treatment. No specific treatment options exist for HAV infection. Treatment efforts are supportive. Fulminant hepatitis is a rare but serious complication of HAV infection, usually requiring hospitalization.

3. Prevention. Hepatitis A vaccination is a highly immunogenic, inactivated vaccine that is administered intramuscularly in the deltoid muscle in a two-shot series 6-12 months apart depending on the vaccine preparation. Hepatitis A vaccine should not be administered to persons with hypersensitivity to alum or components of the vaccine. The following guidelines should be used in administering hepatitis A vaccine to inmates:

(a) Hepatitis A vaccine should be considered for inmates with clotting-factor disorders who are administered clotting-factor concentrates (especially solvent-detergent-treated preparations) and inmates with chronic liver disease or cirrhosis, including HCV infection with underlying liver disease. Hepatitis A vaccine is not routinely indicated for inmates workers who are plumbers or foodworkers.

(b) Natural infection with HAV provides lifelong immunity to reinfection. Vaccination of a person who is immune does not increase the risk of adverse events. Prevaccination serologic screening for previous HAV infection in candidates for vaccination should be considered for certain populations at high risk for previous HAV infection.

(c) Postvaccination serologic testing for immunity is not indicated since the vaccine is highly efficacious.

4. Infection Control Measures. HAV is spread fecal-orally. The virus is stable in the environment for days to several weeks and can be foodborne. Inmates diagnosed with hepatitis A infection should be considered contagious three weeks before to 10 days after the onset of jaundice. The spread of infection is greatly augmented by diarrhea. Inmates diagnosed with acute hepatitis A should be managed in accordance with the following:

(a) Isolated in a single cell with separate sink and toilet (e.g. medical unit, Special Housing Unit) until 10 days after the onset of jaundice and until clinically improving without diarrhea.

(b) Immediately removed from any assigned duties as a food handler.

(c) Counseled regarding the importance of strict hand washing practices.

(d) Cared for by staff using enteric precautions.

(e) Evaluated by health care staff daily and when medically indicated.

(f) Contact with visitors should be limited and permitted, only if recommended by the attending physician and approved by the Warden.

5. Contact Investigation/Post-exposure Management.

(a) Contact investigation should be coordinated with local and state health departments. If the source-case is a food handler, public health officials should be directly involved

in the investigation to evaluate the risk and evidence for food borne disease and subsequent indication for prophylaxis.

(b) The following persons are candidates for post-exposure prophylaxis for hepatitis A if exposed to the source-case during the period of contagiousness:

(1) cell mate(s)

(2) sexual contacts

(3) persons routinely sharing toilet facilities

(4) other food handlers if source-case was food handler

(5) very close contacts such as those who have shared eating utensils and cigarettes

(c) Post-exposure prophylaxis is provided by passive immunization with pooled serum immunoglobulin (IG) in accordance with the following guidelines:

(1) Screening for antibodies to HAV is not recommended so that prophylaxis is not delayed.

(2) IG is administered 0.02 ml/kg intramuscularly (single dose).

(3) IG prophylaxis is not effective unless administered within 2 weeks of exposure.

(4) Persons with prior hepatitis A vaccination or previously documented natural immunity do not require passive immunization with IG.

(5) Hepatitis A vaccination has not been proven to prevent infection following exposure to HAV and is not indicated for post-exposure prophylaxis.

b. Hepatitis B

1. Diagnosis. Screening for HBV infection, by measurement of serum HBsAg, is indicated for all inmates with symptoms of acute or chronic HBV infection and asymptomatic inmates with elevated hepatocellular enzymes of unknown etiology or when otherwise clinically indicated.

Acute hepatitis B. The mean incubation period of HBV infection until the onset of symptoms is 70 days (range: 30-180 days). The severity of acute hepatitis B can range from subclinical to fulminant disease with 5-10% of

patients developing chronic HBV infection. Acute hepatitis B is associated with arthritis, serum sickness, rash, and myelitis. The diagnosis of acute HBV infection is suggested by the presence of HBsAg and is confirmed by the presence of anti-HBc IgM (The latter test is a necessary confirmatory test, since persons chronically antigenemic with HBsAg can be acutely infected with other agents causing hepatitis).

Chronic hepatitis B. The diagnosis of chronic HBV infection is confirmed by the presence of HBsAg, the viral marker indicative of ongoing HBV activity and infectiousness. Infected persons may be asymptomatic. A description of commonly encountered serologic markers in chronic HBV infection include the following:

(a) Elevation of total anti-HBc is always present.

(b) HBeAg may be present and is indicative of ongoing viral replication and increased contagiousness.

(c) Anti-HBs is usually not detected. The presence of anti-HBs when HBsAg is also measurable does not indicate immunity or recovery from disease.

(d) Anti-HBe develops with the loss of HBe antigen.

2. Counseling. Inmates diagnosed with acute or chronic hepatitis B infection should be counseled by a health care provider about the natural history and monitoring of infection, existing treatment options, and specific preventive measures for preventing transmission of HBV infection during incarceration and upon release.

3. Disease Course/Monitoring Chronic Infection.

(a) Highly infectious chronic carriers (HBe+/HBsAg+) develop anti-HBe antibodies at an annual rate of 5-10%. (n.b. associated with transient elevation in hepatocellular enzymes). Development of anti-HBe antibodies indicates a nonreplicative stage of infection. In persons in whom HBeAg disappears, the remission is usually sustained and results in an inactive HBsAg carrier state. Resolution of the chronic carrier state (loss of HBsAg) occurs at an annual rate of approximately 1-2%.

(b) Chronic hepatitis B may be characterized by intermittent episodes of jaundice and the development of cirrhosis. Flares of hepatitis occur with delta superinfection, immunosuppressive treatments or conditions, and interferon alpha therapy. Hepatocellular carcinoma, highly associated with HBV infection, increases in incidence with the duration of infection (median onset - 35 years). Other HBV-related conditions include polyarteritis nodosa and membranous glomerulonephritis.

(c) A baseline physician evaluation should be conducted for all HBV chronic carriers (HBsAg+) and include:

(1) Targeted history and physical examination

(2) Serum aminotransferase concentrations (ALT/AST)

(3) Bilirubin, albumin, prothrombin time if liver enzymes are elevated

(4) Renal function assessment

(5) HBeAg

(d) Periodic clinician evaluations and laboratory studies for HBV chronic carriers should be scheduled and ordered on a case by case basis as clinically indicated depending on the severity of the inmate's liver disease and its associated complications. Screening tests for hepatocellular cancer have an unclear predictive value and are not routinely indicated. Measurement of serum alpha-fetoprotein levels and a liver ultrasound should be considered for inmates with cirrhosis.

3. Treatment

(a) Treatment of acute hepatitis B is supportive. Acute HBV infection may be subclinical, mild, or fulminant.

(b) Interferon-alpha is approved for treatment of chronic HBV infection. Interferon-alpha provides effective treatment for a subset of patients yielding sustained response rates in 25% - 40% of patients treated. Evaluation for drug therapy should be in accordance with Appendix 1 - Algorithm for Treatment of Hepatitis B.

(c) Treatment with interferon should be considered in accordance with the following criteria:

(1) Chronic HBV infection (HBsAg+) documented for at least 12 months duration.

(2) Evidence of active viral replication (HBeAg+) for 12 months.

(3) Chronic liver inflammation documented for 12 months, (elevated serum alanine aminotransferase (ALT) levels at least 1.5 - 2.0 times greater than the upper limit of normal determined by averaging 3 ALT levels each measured at least one month apart over 12 months).

(4) Adequate liver synthetic function - e.g. albumin > 3,

normal prothrombin time, absence of jaundice.

(5) Absence of decompensated cirrhosis: absence of ascites, jaundice, esophageal varices or other evidence of portal hypertension.

(6) WBC > 3,000/cubic ml.
Platelets > 100,000/cubic ml.

(7) Absence of hyperthyroidism.

(8) Absence of autoimmune disease, chronic steroid usage, or solid organ transplantation.

(9) No history of major depression.

(10) No history of other major psychiatric illnesses unless very well controlled by medication.

(11) No evidence of active substance abuse (check urine toxicology screen if drug use suspected).

(12) Age < 60 years.

(13) Informed, motivated inmate (interferon therapy is difficult to tolerate for the patient; duration and side effects of therapy should be fully explained to inmates prior to initiating treatment).

(14) Anticipated incarceration of at least 6 months (inmates who will not predictably complete a course of treatment should receive a baseline evaluation and be referred for medical follow-up and treatment upon release).

(d) Special treatment issues

(1) Renal insufficiency secondary to glomerulonephritis from HBV infection may respond to interferon and is not a contraindication to treatment.

(2) The treatment of persons with hepatitis B and hepatitis C viral co-infections with interferon is relatively contraindicated since safely monitoring the response to treatment and predicting clinical deterioration is difficult.

(3) AIDS or other severe immunosuppressive conditions are relative contraindications for interferon therapy, since response rates are poor. Inmates with HIV and HBV co-infection without AIDS can cautiously be

considered for interferon treatment with a subspecialist.

(e) Prior to initiating treatment, inmates who are candidates for interferon should have serum HBV DNA measured to determine the qualitative presence of detectable HBV levels in the blood. Quantitative HBV DNA measurement is not routinely indicated.

(f) Interferon should only be used as a treatment option for hepatitis B with an initial subspecialty consultation and follow-up subspecialty care as clinically indicated.

(g) Inmates with detectable levels of HBV DNA, who are otherwise candidates for interferon treatment should have a screening liver ultrasound for evidence of other liver pathology. If treatment with interferon is considered, the inmate should be referred for subspecialty evaluation and liver biopsy to confirm the diagnosis of chronic hepatitis, preclude other causes of liver disease, grade the severity of injury, and assess the degree of fibrosis. Interferon treatment should generally not be initiated without a liver biopsy. Interferon treatment should not be prescribed for persons with decompensated cirrhosis, since treatment often exacerbates disease and severe life threatening side effects have been documented.

(h) Prior to initiating interferon treatment the evaluating physician should carefully review the inmate's medical history for conditions that may be contraindications to treatment or significantly complicate treatment. The benefits and toxicities of treatment should be explained to the inmate and documented in the inmate's medical record by the prescribing physician. The recommended treatment regimen for interferon alpha is 5 million units daily or 10 million units thrice weekly given subcutaneously for 4 months. Predictors of a positive response to interferon therapy for hepatitis B include the following:

(1) Short duration of disease

(2) High aminotransferase levels

(3) Low HBV DNA levels

(4) Liver inflammation on biopsy

(5) Fibrosis on liver biopsy

(6) Absence of renal failure, HIV infection, or other serious co-morbidity.

(i) Inmates should receive at a minimum the following baseline evaluations prior to considering interferon therapy:

(1) Physician evaluation and clearance

(2) Psychiatrist or psychologist evaluation and clearance

(3) Serum aminotransferase levels (ALT), albumin, bilirubin, prothrombin time, and creatinine

(4) CBC with differential and platelet count

(5) Thyroid function studies (T4/TSH)

(6) ANA

(7) Serologic assays for HBsAg, HBeAg, and HBV DNA

(8) HCV EIA

(9) Screen for delta hepatitis (anti-HDV) if from a high risk country (e.g. Italy, Middle East, Central Africa) (Delta hepatitis is treated differently than hepatitis B alone).

(10) HIV testing

(j) Treatment with interferon almost universally results in significant side effects for the patient. Prior to beginning treatment the prescribing physician should ensure that the inmate has a thorough understanding of the potential side effects of this therapy. An influenza-like reaction usually evolves within 6 to 8 hours of initiating treatment. This acute reaction normally abates with subsequent treatments and can be partially aborted by premedicating with antipyretics. Chronic side effects of fatigue, myalgia, headaches, irritability, rage, confusion, and neuropsychiatric disorders can occur. Severe incapacitating depression can develop in persons without previous histories of depression. Bone marrow suppression of hematocrit, leukocyte count, and platelet count are serious effects of interferon that should be anticipated and monitored closely. Thyroiditis, hyperthyroidism, and hypothyroidism have been reported in 2.5-20 percent of persons treated and often result in irreversible thyroid dysfunction, even with cessation of drug therapy. Inmates with side effects to interferon should have their dosage reduced or therapy discontinued depending on the severity of the side effects. Very serious sequelae occur with 2% of persons receiving interferon treatment and can include:

cardiac decompensation, renal failure, pneumonitis, severe bone marrow suppression, and suicide.

(k) Inmates should receive at least the following follow-up evaluations during treatment with interferon:

(1) Clinician evaluations before each injection for the first two weeks of treatment and at least biweekly thereafter (Physician evaluations at least monthly).

(2) Subspecialty evaluations as clinically indicated.

(3) Psychiatry or psychology evaluations as clinically indicated during treatment.

(4) ALT weekly for the first two weeks of treatment and monthly thereafter.

(5) Bilirubin, prothrombin time and other liver function studies with new elevations in ALT.

(6) CBC with differential and platelet count weekly for the first month and monthly thereafter.

(7) Thyroid function studies monthly.

(8) Creatinine/electrolytes monthly.

(l) Transient increases in aminotransferase levels are common during therapy and correlate with immune system clearance of HBV and disappearance of HBeAg. Mild to moderate increases in liver enzymes should not be an indication for reducing or discontinuing interferon therapy, unless associated with deteriorating hepatic synthetic function or jaundice.

(m) Loss of HBe antigen after treatment predicts a favorable clinical outcome that may be sustained. Effectiveness of interferon therapy should be assessed 6 months after completion of therapy by measurement of the following parameters:

(1) Absence of HBeAg.
(2) Absence of HBV DNA.
(3) Normalization of ALT.

HBeAg may not return to normal for several months after the completion of interferon treatment. HBsAg may remain positive for years after completion of effective treatment.

(n) Steroids are not indicated for the treatment of chronic hepatitis B infection.

4. Infection Control Measures. Hepatitis B is spread through blood and sexual contact. The following guidelines should be utilized in managing inmates with acute or chronic HBV infection (HBsAg+):

(a) Universal blood and body fluid precautions should be utilized by staff.

(b) Inmates should be counseled during clinical evaluations of the importance of preventing exposures to others during activities of daily living such as sharing toothbrushes and razors and through prohibited behaviors such as sharing injection drug use equipment, tattooing, and sexual contact with other inmates.

(c) Inmates should be counseled on measures for preventing further transmission of HBV infection to others upon their release to the community.

5. Prevention and Post-exposure Management.

(a) Hepatitis B vaccination is routinely indicated (unless medically contraindicated) for the following inmates and staff in accordance with BOP policy and medical indications:

(1) All correctional staff.

(2) Inmate workers at risk for bloodborne pathogen exposure in accordance with the institutional exposure control plan.

(3) Inmates receiving dialysis for chronic kidney disease.

(4) Inmates with HIV infection with risk factors for acquiring HBV infection.

(5) Unprotected staff and inmates as a component of post-exposure prophylaxis in accordance with Centers for Disease Control and Prevention guidelines, following percutaneous or permucosal exposures to infected or potentially infected blood.

(b) Hepatitis B vaccination should be administered in accordance with the following guidelines:

(1) Prevaccination serologic screening for prior HBV infection (measurement of anti-HBc or anti-HBs) is not routinely indicated for staff. For inmates with risk factors for previous HBV infection, such as injection drug use, serologic screening for immunity should be considered.

(2) A previous anaphylactic reaction to baker's yeast, any vaccine component, or previous hepatitis B vaccination is a contraindication to vaccination or booster vaccination.

(3) Based on limited data, hepatitis B vaccine contains no components that have been shown to pose a risk to the fetus or newborn. Pregnancy should not be considered an absolute contraindication to vaccination for women at risk of acquiring HBV infection, since HBV poses a significant risk to the fetus or newborn.

(4) All staff and inmate candidates for vaccination should receive counseling on the administration and potential adverse reactions of hepatitis B vaccination by a physician or otherwise qualified health care provider. Counseling, consent, and declination should be documented as per BOP policy.

(5) The three dose vaccination series is ideally administered at 0, 1, and 6 months, however there is significant flexibility with the administration of the complete series with the following caveats: there must be a 1 month interval between doses #1 and #2; and a 2 month interval between doses #2 and #3; and a 4 month interval between doses #1 and #3. If a dose is delayed the next dose may be administered without restarting the entire series.

(6) The vaccine is administered intramuscularly in the deltoid muscle.

(7) Post-vaccination antibody testing should be offered to all correctional staff 2 months after the completion of the 3 dose vaccination series. Antibody titers may decline as rapidly as 3-6 months following the third vaccine dose.

(8) Correctional workers found to have inadequate antibody levels to HBsAg (< 10 milli-international units of anti-HBs) after the primary vaccine series should be offered the three dose regimen at 0, 1, and 6 months with post-vaccination antibody testing 2 months after the completion of the series. Staff without an adequate serologic response to the second hepatitis B vaccination series will not benefit from further vaccinations and should be classified as nonresponders in their employee health record.

(9) Older men and persons who use tobacco are more likely to be nonresponders. Additionally, employees with

chronic hepatitis B infection (HBsAg+) will be nonresponders. Nonresponders should be appropriately counseled and referred to their physicians. Further serologic testing and evaluation by the employee's physician may be indicated. Vaccine nonresponders will require different post-exposure prophylaxis than responders with exposure to HBV.

(10) Periodic serologic testing for anti-HBs in vaccinated employees is not recommended; nor are routine booster doses of vaccine indicated for initial responders whose antibody levels later decline. Responders who gradually lose antibody over time are still protected from clinically significant hepatitis B infection by the immune system's ability to limit or thwart infection at the time of exposure.

(11) Staff who have completed their vaccination series more than 6 months ago should not be offered antibody testing, since a negative antibody test result more than 2-6 months after completing vaccination can not be interpreted accurately and may represent either nonresponse or the loss of detectable antibody.

(12) Previously vaccinated correctional staff with unknown antibody status who receive post- exposure prophylaxis with a booster dose of hepatitis B vaccine should have anti-HBs measured 2 months after the booster vaccination to establish their responder status.

(13) Staff and inmates with exposures to HBV-infected blood should be counseled by a health care provider regarding the transmission risk, incubation period for acute hepatitis B, the natural history of HBV infection; and the recommendations for post-exposure prophylaxis. Prompt post-exposure prophylaxis with hepatitis B immunoglobulin and/or hepatitis B vaccine should be provided to inmates and staff when indicated in accordance with Appendix 2, Post-exposure Prophylaxis for Hepatitis B Infection and Centers for Disease Control and Prevention (CDC) guidelines. All staff should be referred for medical evaluation and follow-up.

c. Hepatitis C

1. Diagnosis. Screening for HCV infection by measurement of anti-HCV by EIA, should be considered for any inmate with elevated hepatocellular enzymes or unknown etiology or signs and symptoms of hepatitis or any of the following: history of injecting illicit drugs, recipient of blood

transfusion or organ transplant before 1992, recipient of clotting factor transfusion prior to 1987, or a history of hemodialysis.

For inmates with risk factors for HCV infection and elevations in hepatocellular enzymes, a positive EIA is sufficient to initially diagnose HCV infection. A qualitative assay of serum HCV RNA, however, should be obtained for confirmation of infection before initiating antiviral treatment. For inmates with normal hepatocellular enzymes or no risk factors for HCV infection, a positive EIA should always be confirmed by a supplementary RIBA.

(a) Acute hepatitis C. The mean incubation period to onset of symptoms after HCV infection is 7 weeks (range 3-20 weeks). Compared to other forms of acute viral hepatitis, acute hepatitis C is often a mild infection with a self-limited course. The infection is subclinical in two-thirds of cases. Fulminant acute hepatitis C is rare. Acute HCV is cleared in 15%-25% of infected persons, while 75%-85% of infected persons develop chronic HCV infections of varying severity. The diagnosis of acute viral hepatitis C is based on a positive anti-HCV EIA, and clinical or laboratory evidence of acute hepatitis, without evidence of other viral or noninfectious causes of acute hepatitis.

(b) Chronic hepatitis C develops in 75%-85% of persons infected with HCV. Although antibodies to HCV are measurable with chronic infection the antibodies do not prevent progression of disease or protect an infected individual from new HCV infections.

2. Disease Course/Monitoring Chronic Infection

(a) Chronic HCV infection has a waxing and waning natural history with frequent fluctuations in liver function tests and recurrent bouts of hepatitis. Studies of persons with chronic hepatitis C indicate that viral replication and active infection occur in the presence of anti-HCV antibodies with or without evidence of liver function abnormalities. Approximately one-third of persons with chronic HCV infection will have subclinical hepatitis with persistently normal serum ALT levels. The majority of persons with chronic HCV infection have abnormal serum ALT levels that fluctuate widely over time. Progression to cirrhosis occurs unpredictably, but increases with duration of infection; and although serum ALT levels do not correlate strongly with histologic progression of disease, persons who develop cirrhosis are more likely to have marked elevations in serum ALT levels. An estimated 10% to 20% of persons infected with HCV ultimately develop cirrhosis or clinically significant hepatic disease. Persons with chronic HCV infection are asymptomatic 80% of the time. Fatigue is the most common

presenting complaint, but often symptoms do not become apparent until the infected person has developed cirrhosis and the associated complications of liver failure.

(b) HCV infection can be complicated by hepatocellular carcinoma usually in the presence of cirrhosis after longstanding infection of 3 or more decades. Non-hepatic manifestations of HCV infection include essential mixed cryoglobulinemia (frequently presenting as renal failure), membranoproliferative glomerulonephritis, and porphyria cutanea tarda. The presentation of these clinical conditions should prompt evaluation for HCV infection.

(c) A baseline physician evaluation should be conducted for all inmates diagnosed with HCV infection and include at least the following:

(1) Targeted history and physical examination.

(2) Serum ALT/AST.

(3) Serum albumin, bilirubin, and prothrombin time if aminotransferases are elevated.

(4) Renal function assessment.

(d) Periodic clinician evaluations and laboratory studies should be scheduled and ordered on a case by case basis depending on the severity of HCV infection and its complications. Screening tests for hepatocellular cancer have unproven predictive value and are not routinely indicated. For inmates with documented cirrhosis or infection of longstanding duration (> 25 years), measurement of serum alpha-fetoprotein levels and liver ultrasound should be considered.

3. Treatment

(a) FDA-approved regimens with proven efficacy for the treatment of hepatitis C include interferon preparations alone or combination therapy with interferon and ribavirin. Both regimens have significant toxicities. Ribavirin is completely ineffective as monotherapy and should never be prescribed without interferon. Drug therapy for HCV infection should only be considered with the complete physician and patient understanding of the following:

(1) Only 10%-20% of persons with HCV infection have developed significant long term complications of liver disease, 20-30 years after initial infection.

(2) Current drug therapies have notable toxicities that significantly reduce quality of life during therapy and can be life threatening.

(3) No clinical or laboratory parameters definitively predict which persons infected with HCV will develop cirrhosis or respond to medical therapy. Persons with a history of excessive alcohol consumption and who are infected at > 40 years of age are at greater risk of cirrhosis.

(4) Interferon alpha (3 million units administered subcutaneously 3 times/week for 12 months) alone as initial treatment for HCV infection is approximately 10-25% effective in producing a sustained virologic response.

(5) Interferon and ribavirin combination therapy is approximately 40-50% effective in producing a sustained virologic response, but has greater toxicities than interferon alone.

(b) Evaluation of inmates for medical treatment of HCV infection should be considered in accordance with Appendix 3 - Algorithm for Treatment of Hepatitis C.

(c) Drug therapy should be considered with an understanding of the medical contraindications to interferon and ribavirin treatment enumerated in Appendix 4, Contraindications to Interferon and Ribavirin, and the following criteria:

(1) Chronic liver inflammation for at least 12 months (sustained ALT 1.5 to 2 times greater than the upper limit of normal determined by averaging serum ALT levels on three different occasions measured at least one month apart over 12 months).

(2) Adequate liver synthetic function - e.g. albumin > 3, normal prothrombin time, absence of jaundice.

(3) Absence of compensated or decompensated cirrhosis.

(4) WBC > 3,000 cells/cubic ml.
Platelets > 100,000/cubic ml.

(5) Absence of hemogloblinopathies, hemolysis, or severe anemia (hemogolobin < 12 gm/dl for females and < 13 gm/dl for males) if prescribed ribavirin.

(6) Absence of hyperthyroidism.

(7) Absence of autoimmune disease, chronic steroid usage, or history of solid organ transplantation.

(8) Absence of cardiovascular disease if prescribed ribavirin.

(9) Negative pregnancy test for women if prescribed ribavirin. (Women of childbearing potential and men must use effective contraception during treatment and during the six-months post-treatment follow-up period when taking ribavirin).

(10) No history of major depression.

(11) No history of other major psychiatric illness unless very well controlled.

(12) No evidence of active substance abuse (check urine toxicology screen if drug use suspected).

(13) Age < 60 years (Persons over 60 years of age can be cautiously considered for treatment on a case by case basis in consultation with a subspecialist, but may be at greater risk for life threatening complications).

(14) Highly motivated patient (the lengthy duration and significant side effects of treatment should be explained to the inmate to assess anticipated compliance with therapy).

(15) Anticipated incarceration of at least 12 months (inmates who will not predictably complete a course of treatment should receive a baseline evaluation and be referred for medical follow-up and treatment upon release).

(d) Special treatment considerations.

(1) HIV infection, particularly complicated by AIDS, is a relative contraindication for drug treatment of hepatitis C, since response to therapy is poor and current treatments are investigational. Treatment of inmates with HIV and HCV without AIDs can be considered cautiously, in consultation with a specialist.

(2) Interferon does have efficacy for treatment of chronic HCV infection complicated by mixed essential cryoglobulinemia. Treatment should be considered in consultation with subspecialists.

(3) Drug therapy for persons with chronic HBV and HCV

coinfections is relatively contraindicated since the response to therapy is unpredictable and difficult to safely monitor.

(e) Prior to initiating drug treatment, inmates who are candidates for interferon should have qualitative HCV RNA serologically measured to confirm the presence of HCV infection.

(f) Drug therapy should be used as a treatment option only with an initial subspecialty consultation and follow-up subspecialty care as clinically indicated.

(g) Inmates with detectable HCV RNA, who are otherwise candidates for drug therapy should have a liver/abdominal ultrasound to screen for the presence of other medical conditions that may affect or preclude treatment.

(h) Inmate candidates for drug treatment should be referred for subspecialty evaluation and liver biopsy to confirm the diagnosis of hepatitis, preclude other causes of liver disease, grade the severity of injury, and assess the degree of fibrosis.

(i) Drug treatment is absolutely contraindicated for persons with decompensated cirrhosis, since treatment often exacerbates disease resulting in severe life threatening sequelae.

(j) Inmates should receive the following baseline evaluations prior to considering drug treatment:

(1) Physician evaluation and clearance.

(2) Psychiatrist or psychologist evaluation and clearance.

(3) Serum aminotransferase levels (ALT), albumin, bilirubin, prothrombin time, and creatinine.

(4) CBC with differential and platelet count.

(5) Thyroid function studies (T4/TSH).

(6) ANA.

(7) HBsAg.

(8) HIV antibody testing.

(k) Interferon is administered subcutaneously, usually for 12 months of therapy. Various formulations of interferon with differing dosage regimens have been federally-approved for

the treatment of hepatitis C. The specific interferon formulation/dosage regimen should be determined after review of current efficacy data in consultation with a physician with expertise in treating hepatitis C.

(l) Treatment with interferon almost universally results in significant side effects. The treating physician should ensure that the inmate is aware of all potential side effects prior to prescribing therapy. An influenza-like reaction usually evolves within 6 - 8 hours of initial treatment with interferon alpha. This acute reaction normally abates with subsequent treatments and can be partially aborted by premedication with antipyretics. Chronic side effects of fatigue, myalgia, headaches, irritability, rage, confusion, and neuropsychiatric disorders can occur. Severe incapacitating depression can develop in persons without a previous history of depression. Bone marrow suppression of hematocrit, leukocyte count, and platelet count are serious effects of interferon that should be anticipated and monitored closely. Thyroiditis, hyperthyroidism, and hypothyroidism have been reported in 2.5-20% of persons treated with interferon and often result in thyroid dysfunction, even with cessation of drug therapy. Inmates with side effects to interferon should have their dosage reduced or therapy discontinued depending on the severity of the side effects. Very serious sequelae of interferon treatment occur in 2% of patients and may include cardiac decompensation, renal failure, pneumonitis, severe bone marrow suppression, and suicide.

(m) Treatment with ribavirin in combination with interferon should be considered on a case by case basis depending on inmate preference, contraindications to treatment, and drug tolerance. Ribavirin is prescribed as 400 mgs (two, 200 mg capsules) taken orally in the morning and 600 mgs (three, 200 mg capsules) taken orally in the evening for persons weighing 75 kg or less; and 600 mgs (three, 200 mg capsules) taken orally in the morning and 600 mgs (three, 200 mg capsules) taken orally in the evening for persons weighing over 75 kg.

(n) Anemia, usually from hemolysis occurs in at least 10% of persons taking ribavirin and can develop acutely, potentially resulting in serious complications.

(o) Inmates should receive at least the following evaluations during drug treatment for HCV infection:

(1) Clinician evaluations before each injection of interferon for the first two weeks of treatment and at least every 2 weeks thereafter (physician evaluations at least monthly).

(2) Subspecialty evaluations as clinically indicated.

(3) Psychiatry or psychology evaluations when clinically indicated.

(4) ALT weekly for the first four weeks of treatment and monthly thereafter.

(5) Bilirubin, prothrombin time and other liver functions studies with new elevations in ALT.

(6) CBC with differential and platelet count weekly for the first month of treatment and monthly thereafter (CBC should be measured every two weeks after the first month of treatment for inmates receiving ribavirin).

(7) Thyroid function studies monthly.

(8) Creatinine/electrolytes monthly.

(9) Fundoscopic evaluation for inmates with diabetes or hypertension at baseline, repeated with any complaints of vision problems during treatment.

(p) An uncommon, but clinically pertinent side effect of interferon treatment of hepatitis C is worsening of hepatitis. New elevations in ALT serum levels during treatment of HCV infection can herald liver failure and are an indication for immediate cessation of therapy.

(q) Inmates who have a decline of serum ALT levels to normal or near normal within 8 to 12 weeks of treatment with interferon or interferon and ribavirin should be maintained on treatment since a sustained remission is probable. Interferon alone is usually prescribed for 12 months of treatment. Interferon and ribavirin are usually prescribed for a total of 6-12 months of treatment.

(r) Inmates who do not demonstrate a decline in ALT levels to normal or near normal within 8-12 weeks should be re-evaluated for possible cessation of drug treatment, since a sustained virologic remission is unlikely. Prior to discontinuing treatment, HCV RNA should be measured to confirm the continued presence of viremia.

(s) Inmates who initially responded to anti-viral drug therapy and then relapsed may be candidates for retreatment. Retreatment should be considered in consultation with a specialist. Retreatment with interferon or interferon/ribavirin combination therapy is not indicated for

inmates with HCV infection who never responded to previous anti-viral drug therapy.

(t) Quantitative HCV RNA assays and serial liver biopsies are not routinely indicated for monitoring the response to drug treatment.

(u) Steroids should not be prescribed for treatment of chronic HCV infection.

4. Infection Control Measures. HCV is spread primarily through parenteral blood exposures. HCV is inefficiently transmitted through sexual contact, however, persons with a history of sexually transmitted diseases, do have an increased risk of HCV infection. The following guidelines should be utilized in managing inmates with HCV infection:

(a) Universal blood and body fluid precautions should be utilized by staff for management of all exposures to blood involving inmates.

(b) Inmates with HCV infection should be counseled by a qualified health care provider on the importance of preventing exposures to others during activities of daily living such as sharing toothbrushes and razors and through prohibited behaviors such as sharing injection drug use equipment, tattooing, and sexual contact with other inmates.

(c) Inmates with HCV infection should be counseled on measures for preventing further transmission of HCV infection to others upon their release to the community.

5. Post-exposure Management. Staff and inmates with percutaneous or permucosal blood exposures to HCV should be counseled by a qualified health care provider about the transmission, incubation, and natural history of HCV infection in accordance with CDC guidelines. No vaccine, passive immunization, or anti-viral treatments are available to abort or treat newly acquired HCV infection following an exposure. Contacts should be referred for medical evaluation and follow-up. Anti-HCV antibodies by EIA (confirmed by RIBA, if positive) and alanine aminotransferase (ALT) hepatic enzymes should be measured at 0 and 6 months following an exposure to screen for newly acquired HCV infection. Inmates and staff with evidence of newly acquired HCV infection should be appropriately counseled and referred for further medical evaluation.

d. Hepatitis D

1. Diagnosis. Hepatitis D (delta) viral co-infection or superinfection occurs only in the presence of active hepatitis B infection (HBsAg+). Inmates at highest risk for delta hepatitis have a history of injection drug use or have resided in an area of the world with a high prevalence of infection such as Middle East countries, Italy and Central

Africa.

(a) Acute delta hepatitis can be diagnosed by the presence of anti-HDV IgM, however, this antibody may be present only transiently.

(b) Chronic delta hepatitis can be diagnosed by the presence of anti-HDV IgM and anti-HDV (total). Anti-HDV IgM is a marker for ongoing viral activity/hepatitis. The presence of anti-HDV (total) indicates remote infection with hepatitis D virus, but not necessarily active infection.

2. Disease Course/Monitoring Chronic Infection

(a) Acute delta co-infection usually presents as a mild to moderate hepatitis that resolves without development of chronic hepatitis.

(b) Acute delta superinfection often presents as a severe hepatitis that resolves, then recurs as chronic delta hepatitis with a rapid progression to cirrhosis and its associated complications.

(c) Periodic clinician evaluations should be conducted for inmates with chronic HDV infection in accordance with guidelines for monitoring chronic hepatitis B. Persistence of chronic delta hepatitis can be assessed by measurement of anti-HDV IgM.

3. Treatment. Treatment of acute delta hepatitis is primarily supportive. Inmates with chronic delta hepatitis should be considered as candidates for interferon therapy using the treatment criteria for managing inmates with chronic HBV infection. The treatment regimen for treating delta hepatitis with interferon, however, differs from the regimens for both hepatitis B and hepatitis C. Treatment should be prescribed and monitored only in consultation with a subspecialist.

4. Infection Control. Hepatitis D virus is transmitted primarily through parenteral blood exposure. Infection control measures applicable for HCV should be utilized for controlling the spread of HDV.

5. Post-exposure Management. Inmates and staff with blood exposures to hepatitis D should be counseled on the transmission, incubation, and natural history of HDV infections. Although no vaccine, passive immunization, or anti-viral treatments are available to specifically abort or treat newly acquired HDV infection, HDV can not newly infect an individual if infection with HBV is prevented with hepatitis B immunoglobulin/hepatitis B vaccine in accordance with CDC guidelines. Contacts who are HBV chronic carriers (HBsAg+) should be counseled on the risk for delta superinfection that can result in severe hepatitis. Inmate contacts should be monitored closely for exacerbations of their liver

disease. Staff contacts should be provided prophylaxis for HBV infection when medically indicated and counseled and referred for medical evaluation and follow-up.

ATTACHMENTS.

Appendix 1. Algorithm for Treatment of Hepatitis B

Appendix 2. Post-exposure Prophylaxis for Hepatitis B

Appendix 3. Algorithm for Treatment of Hepatitis C

Appendix 4. Contraindications for Interferon and Ribavirin Treatment of Viral Hepatitis

Appendix 1

Algorithm for Antiviral Treatment of Hepatitis B

HBsAg+
HBe+

↓

ALT 1.5-2 x normal x 3 over 12 months

↓

Physician clearance
No evidence of decompensated cirrhosis
No contraindications to interferon tx
Anticipated incarceration > 6 months

↓

Psychiatry or psychology clearance

↓

Viremic- HBV DNA+

↓

Screening liver ultrasound

↓

Subspecialty evaluation
Liver biopsy

↓

Consider interferon tx if indicated

Appendix 2

Postexposure Prophylaxis for Percutaneous or Permucosal Exposure* to Hepatitis B Virus †

Vaccination Status/Antibody Response	Treatment Based on Source's Hepatitis B Viral Infection Status		
	HBsAg positive	HBsAg negative	Status Unknown
Unvaccinated	HBIG** X 1; Initiate HB vaccine series	Initiate HB vaccine series	Initiate HB vaccine series
Vaccinated - Known Responder***	No treatment	No treatment	No treatment
Vaccinated - Known Non-responder	HBIG X 2; OR HBIG X 1 and revaccination series	No treatment	If known high-risk source, treat as if source were HBsAg positive
Vaccinated - Unknown Response Status	Test exposed person for anti-HBs: If adequate - no treatment If inadequate - HBIG X 1 PLUS vaccine booster	No treatment	Test exposed person for anti-HBs: If adequate - no treatment If inadequate - initiate revaccination

* Exposure is percutaneous (laceration, needlestick, bite) or permucosal (ocular or mucous-membrane) contact with blood.

** Hepatitis B immune globulin (HBIG) dose is 0.06 ml/kg administered intramuscularly at different site than vaccine preferably within 24 hours of exposure; efficacy > 7 days after exposure is unknown.

*** Adequate anti-HBs levels is ≥10 mIU/ml.

† Adapted from CDC guidelines, MMWR, Vol. 46, No. RR-18

Appendix 3

Algorithm for Treatment of Hepatitis C

Anti-HCV+ by EIA (high risk)
Anti-HCV+ by RIBA (low risk)

⇓

ALT 1.5-2 x upper limit of normal x 3 over 12 months

⇓

Physician clearance
No evidence of decompensated cirrhosis
No contraindications to interferon tx
Anticipated incarceration > 12 months

⇓

Psychiatry or psychology clearance

⇓

HCV RNA+

⇓

Screening liver ultrasound

⇓

Subspecialty evaluation
Liver biopsy

⇓

Consider interferon tx or interferon/ribavirin tx

Appendix 4

Contraindications for Interferon or Ribavirin Therapy*

INTERFERON

Absolute Contraindications:

Normal ALT
Decompensated cirrhosis - e.g. albumin < 3, jaundice, ascites, varices, coagulopathy
Marrow dysfunction - WBC < 3,000/mm^3, neutrophils < 1,500/mm^3, platelets < 100,000/mm^3
Hyperthyroidism
Autoimmune disease or chronic steroid usage
Solid organ transplantation
History of major depression
Active illicit drug usage

Relative Contraindications:

Age > 60 years
History of psychiatric diagnoses
HIV infection
Hepatitis B and C coinfections
Diabetes - Hemoglobin A_{1c} > 8.5%
Renal insufficiency; creatinine clearance < 50 ml/min

RIBAVIRIN

Absolute contraindications

Pregnancy - due to risk of fetal malformations and fetal death (pregnancy test required prior to initiating therapy; and women of childbearing potential and men must use effective contraception during treatment and during the six-months post-treatment follow-up period)

Hemogloblinopathies, hemolytic anemias or other severe anemias; with hemoglobin < 12 gm/dl for females and < 13 gm/dl for males

Ischemic cardiovascular disease or cerebrovascular disease

***Refer to drug manufacturer's warnings in addition to highlighted contraindications**

FEDERAL BUREAU OF PRISONS TREATMENT GUIDELINES FOR HIV INFECTION

PURPOSE. The BOP Treatment Guidelines for HIV Infection provide guidelines for the medical management and monitoring of federal inmates diagnosed with HIV infection.

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1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults, *MMWR*, Vol. 41, No. RR-17, December 18, 1992, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta, Georgia.

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Report of the NIH Panel to Define Principles of Therapy of HIV Infection and Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents, *MMWR*, Vol. 47, No. RR-5, April 24, 1998, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta, Georgia.

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DEFINITIONS.

Clinician is a physician or mid-level provider.

EIA is Enzyme Immunoassay, a test for detecting antibodies.

PROCEDURE.

a. Diagnosis

1. The following inmates are at high risk for HIV infection or have clinical indications for HIV testing and should be considered for diagnostic evaluation when incarcerated or whenever risk factors for HIV infection are identified:

(a) Injection drug users.

(b) Men who have had sex with men.

(c) Regular sex partners of persons at risk for HIV infection.

(d) Inmates with a history of syphilis or other sexually transmitted diseases.

(e) Hemophiliacs and any inmate who has received blood products from 1977 - May, 1985.

(f) Pregnant women.

(g) Persons with active tuberculosis or a positive tuberculin skin test.

(h) Inmates with signs or symptoms of acute HIV infection or HIV-related conditions.

2. All inmates tested for HIV infection shall receive individual, confidential, pretest and post-test counseling by qualified health care personnel in accordance with BOP policy.

3. The diagnosis of HIV infection is determined by a positive EIA for HIV antibodies that is confirmed by immunoblot (Western blot) analysis. Inmates newly diagnosed with HIV infection who have undetectable HIV RNA should have a second HIV antibody test by EIA and Western blot analysis to confirm the presence of infection.

4. Inmates who test positive for HIV infection should be referred to a physician for baseline evaluation within one month of diagnosis unless more expedient medical evaluation is clinically indicated.

5. An indeterminant test result for HIV-1 infection is associated with the following conditions:

(a) Process of HIV seroconversion.

(b) HIV-2 infection (West African, travel to West Africa, or high risk contact with West African).

(c) History of blood or blood product transfusions.

(d) Organ transplantation.

(e) Pregnancy.

(f) Autoimmune disease.

(g) Malignancy.

(h) Recipients of HIV experimental vaccines.

(i) Advanced HIV infection (AIDS).

6. Indeterminant results include a positive EIA, usually with a single p24 band on Western blot analysis. Inmates with indeterminant HIV test results should be referred to a physician for further evaluation in accordance with the following guidelines:

(a) Physician interview for HIV infection risk factors, symptoms of HIV infection and AIDS, and causes of indeterminant HIV test results.

(b) Physician evaluation of the inmate for conditions that may result in an indeterminant test result when clinically indicated based on the inmate’s history and examination.

(c) Repeat HIV testing in 3 and 6 months.

(d) If the HIV test result remains indeterminant at 6 months, BOP medical referral center laboratory personnel should be consulted for further evaluation of the test results.

7. All inmates newly diagnosed with HIV infection shall be classified in accordance with the most recent Centers for Disease Control and Prevention (CDC) guidelines and BOP policy. HIV risk factors and classification shall be documented on the Federal Bureau of Prisons HIV Classification Form, Appendix 1. Reclassification and updated documentation is required only when inmates progress to a more advanced stage of HIV infection, not during each evaluation or with clinical improvement.

b. Medical Evaluation and Treatment.

1. Baseline Evaluation: Baseline evaluation by a physician for inmates diagnosed with HIV infection should include the following as outlined in Appendix 2:

(g) Medical history including assessment of HIV risk factors.

(b) Physical examination including pelvic examination and PAP smear for women.

(c) Referral for dental examination by a dentist for all inmates.

(d) Psychology referral if clinically indicated (in addition to mandatory referral made as part of post-test counseling)

(e) Baseline laboratory studies and immunizations including:

(1) CBC/platelet count.

(2) CD4+ T-lymphocyte cell count and percentage.

(3) Plasma HIV RNA measurement using FDA-approved method.

(4) Serum electrolytes/creatinine/liver function studies.

(5) RPR/FTA - treatment history review.

(6) Toxoplasmosis IgG titer.

(7) Hepatitis serologies - if liver function studies are elevated assay HBsAg and anti-HCV by EIA for coinfections with HBV or HCV respectively.

(8) Tuberculin skin test/symptom review for TB symptoms.

(9) Chest radiograph to evaluate for occult TB or other pathology.

(10) Pneumococcal vaccine: .5 ml IM x 1 with revaccination at 5 years.

(11) Influenza vaccine: annually

(12) Hepatitis B vaccine: for inmates at risk for acquiring HBV infection (prevaccination serologic screening for prior infection by measuring anti-HBs or anti-HBc antibodies should be considered).

(f) Comprehensive treatment plan, including subspecialty referrals as clinically indicated.

2. Periodic Evaluations: Periodic medical evaluations for inmates with HIV infection should be conducted by a clinician at least quarterly, including a physician evaluation at least semiannually for inmates receiving anti-retroviral therapy. Immunologic status should be assessed by the measurement of the CD4+ T-cell count and plasma HIV RNA using FDA-approved testing methods in accordance with current CDC guidelines. Clinician evaluations, CD4+ T-cell count assessments and HIV plasma RNA measurements should be based on the inmate's immune status as outlined in Appendix 2. The indications and frequency of other laboratory monitoring will depend on the inmate's antiretroviral treatment regimen and prophylactic regimen for opportunistic infections (Key monitoring parameters are outlined in Appendices 3-6). Inmates should be reclassified according to CDC criteria if they progress to a more advanced stage of infection.

3. CD4+ T-Cell Assays: The measurement of CD4+ T-cells is essential for immunologic staging of inmates with HIV infection and for therapeutic monitoring and initiation of prophylaxis for opportunistic infections associated with HIV infection. The CD4+ T-cell count may decline with intercurrent illnesses and steroid administration. Splenectomy increases CD4+ T-cell counts. In addition, diurnal and analytical variations in measuring CD4+ T-cells are common; CD4+ T-cell counts are subject to significant variability and can vary up to 30 percent on repeated measures in the absence of a change in the patient's clinical condition. Any changes in the absolute number of CD4+ T-cells should be reviewed to determine if the percentage of CD4+ T-cells has also comparatively changed, since a decline in the absolute WBC count that is not related to HIV infection will often be reflected in a decline in CD4+ T-cells, while the percentage of CD4+ T-cells remains nearly constant.

4. Quantitative Plasma HIV RNA Assays: The measurement of plasma HIV RNA is clinically essential for monitoring the response to anti-retroviral therapy. The HIV viral burden should be measured before and 3-4 weeks after any initiation or change in antiretroviral treatment and routinely in accordance with Appendix 2. The maximal antiviral effect is usually observed after 4 to 6 months of antiretroviral treatment. The same laboratory using the same HIV RNA assay should be utilized whenever possible to minimize test variability. The measurement of HIV viral burden within one month of an acute illness or immunization should be avoided due to false elevations.

5. Ancillary Monitoring Parameters: The measurement of p24

antigen, neopterin, and $-2 microglobulin levels are less reliable than plasma HIV RNA assays and do not add significant prognostic information for the clinician; and therefore are not routinely indicated. HIV phenotypic and genotypic assays can predict drug resistance, but are considered investigational and not routinely indicated since their clinical utility has not been established.

6. Indications for Antiretroviral Therapy: Inmates with elevated plasma HIV RNA levels or depressed CD4+ T-cell counts, or evidence of AIDS should be offered antiretroviral treatment in accordance with Appendix 2. Inmates with CD4+ T-cells $\geq$ 350/mm^3 with elevated viral loads who have never received anti-retroviral treatment, should have the elevated viral load confirmed with a second measurement prior to initiating first time anti-retroviral therapy. Inmates with viral loads < 20,000 cps/ml (RT-PCR) with CD4+ T-cells of 200-499/mm^3, should have the depressed CD4+ cell count confirmed with a second measurement prior to initiating first time anti-retroviral therapy.

7. Antiretroviral Therapy: Antiretroviral therapy should be provided to inmates in accordance with the most recent Department of Health and Human Services (DHHS) recommendations and the guidelines outlined in Appendices 2-5. The prescription of antiretroviral therapy should be based on the inmate's immunologic status, prior treatment history, potential drug toxicities, length of anticipated incarceration, inmate motivation, and inmate history of previous adherence to medical treatments. Since strict adherence to antiretroviral therapy is necessary for drug effectiveness and preventing drug resistance, inmate education by clinician, pharmacy and nursing staff is critical. Mental health conditions should be evaluated, treated, and stabilized, prior to initiating complex antiretroviral therapies.

8. Monitoring Therapy: All decisions to initiate, change, or discontinue anti-retroviral medications should be made by a physician or in consultation with a physician. The goal of treatment is to reduce HIV viral burden as much as possible, (preferably to undetectable levels) for as long as possible. The viral load nadir is correlated with the effectiveness of treatment and is reached 4-6 months after initiating or changing therapeutic regimens. A 10 fold change (1 log decline) at one month, roughly predicts an ultimate HIV RNA nadir of < 500 cps/ml. Treatment failure is suggested by a rapid decline in the CD4+ T-cell count or clinical deterioration and is confirmed by a return of plasma HIV RNA to pretreatment levels. Treatment decisions should not be made based on one CD4+ T-cell measurement due to testing variability. In cases in which the CD4+ T-cell count and plasma HIV RNA levels appear to be inconsistent, prophylaxis for opportunistic infections should be managed according to the CD4+ T-cell count, and anti-retroviral therapy decisions should be based on the viral burden.

9. Changing and Discontinuing Antiretroviral Therapy: Changing antiretroviral therapy should be initiated cautiously based on the response to drug therapy as determined by plasma HIV RNA levels. Treatment should

usually be changed when the HIV RNA burden does not reach undetectable levels after 6 months of initiating therapy. For inmates who do not reach undetectable HIV RNA levels due to drug toxicities, viral resistance, or nonadherence to therapy, changing a suboptimal treatment regimen may not be feasible or advised. Therapy with antiretroviral medication should usually not be discontinued despite a suboptimal response, since partial HIV suppression results in improved clinical outcomes of uncertain long term benefit. Inmates nonadherent to antiretroviral therapy should be monitored by daily direct observation of drug administration with ongoing counseling and referral to the Clinical Director for review (The decision to continue, change, or stop antiretroviral therapy must be made on a case by case basis for inmates nonadherent to therapy). The decision to discontinue antiretroviral therapy for terminally ill inmates with AIDS who are not responding to therapy should be made by the inmate and the treating physician. For terminally ill inmates, continuing antiretroviral medications, may provide little clinical benefit and negatively impact on the inmate's quality of life.

10. Prophylaxis of Opportunistic Infections: Prophylaxis of opportunistic infections should be prescribed in accordance with the most recent U.S. Public Health Service recommendations and the BOP guidelines as outlined in Appendix 6. Prophylaxis of opportunistic infections should usually not be discontinued if CD4+ T-cells counts improve with antiretroviral therapy, since immune function may still be compromised.

11. Subspecialty Consultation: An infectious disease consultant or other physician with expertise in treating HIV infection should be consulted when possible to assist in the management of inmates with HIV infection, particularly for the following cases:

(a) Inmates who fail initial anti-retroviral therapy requiring a change in treatment regimens.

(b) Inmates with active tuberculosis and HIV infection.

(c) Pregnant women with HIV infection.

(d) Inmates with suspected acute HIV infection

12. Pregnancy: All pregnant women should be tested for HIV infection with or without known risk factors for HIV infection. Pregnant inmates with HIV infection should be counseled on the effectiveness of zidovudine (AZT) in reducing the perinatal transmission of HIV infection and the most current U.S. Public Health Service recommendations for treating the mother. Pregnancy itself should not preclude optimal antiretroviral regimens, however, the potential known and unknown effects of antiretroviral medications on the mother, fetus, and newborn child, must be considered. Antiretroviral treatment decisions should be made on a case by case basis by the inmate and her physicians after careful consideration of known risks and benefits. Pregnant women who refuse medically indicated antiretroviral therapy should be referred for psychologic evaluation and

further review by the Clinical Director.

c. Documentation of Medical Treatment. Documentation of medical care provided to inmates with HIV infection should be maintained in accordance with the following:

1. CDC initial and updated HIV classifications documented on the Federal Bureau of Prisons HIV Classification Form, Appendix 1.

2. Baseline and periodic clinician evaluations documented on the Federal Bureaus of Prisons HIV Chronic Care Clinic Flowsheet, Appendix 7.

3. Treatment plans for baseline and periodic clinician evaluations documented in medical record progress notes.

d. HIV Post-exposure Treatment

1. Medical Management. BOP employees and inmate workers who experience occupational-related exposures to HIV infected blood or other potentially infectious materials (OPIM) shall be provided emergent counseling and treatment by a qualified health care professional in accordance with the following:

(a) The injured skin or wound should be emergently cleansed with soap and running water for two minutes. Mild bleeding should be allowed to continue. Antiseptics, bleach, or other cleansing agents should not be used. Aspiration, forced bleeding, and wound incision are not recommended. Mucous membranes should be rinsed with water for two minutes. Exposed eyes should be flushed with water or saline for two minutes.

(b) The evaluating health care professional should interview the injured worker to determine if a potential occupational exposure to HIV has occurred in accordance with current CDC guidelines. Post-exposure prophylaxis is indicated depending on the severity of exposure and HIV status of the source. Post-exposure prophylaxis is usually not indicated if the source of the exposure is not HIV-infected, unless there is evidence that the source-person had clinical evidence of HIV infection (e.g. acute retroviral-illness, signs or symptoms of HIV infection) or recent high risk activity for acquiring HIV infection). The person whose blood or body fluids are the source of an occupational exposure should be evaluated for HIV infection in accordance with CDC guidelines and BOP policy. Blood and the following substances are considered potentially infectious for HIV: semen, vaginal secretions, cerebrospinal fluid, pleural fluid, peritoneal fluid, synovial fluid, un-fixed tissue, certain lab specimens, and any substance contaminated by visible blood. Exposure to visibly uncontaminated urine, feces, and saliva does not

require HIV post-exposure prophylaxis. Human bites involving blood are considered percutaneous blood exposures.

(c) If an exposure or questionable occupational exposure to HIV has occurred, the evaluating health care professional should immediately review the incident with the Clinical Director or other physician designee to validate the exposure and determine if HIV post-exposure treatment is to be recommended, to be considered, or may not be warranted in accordance with CDC guidelines, outlined in Appendix 8, HIV Post-exposure Prophylaxis Guidelines.

(d) The evaluating health care professional shall provide counseling to the exposed employee regarding HIV post-exposure indications in accordance with BOP physician orders and CDC guidelines.

(e) If no medical contraindications to treatment are identified, the BOP employee should be given a prescription of HIV anti-retroviral medications, not to exceed an emergency four day supply; or should be emergently referred to a community medical provider, if timely treatment can reasonably be assured (CDC guidelines recommend that HIV post-exposure prophylaxis be administered promptly, preferably within a few hours of exposure). Anti-retroviral medications may only be dispensed and administered to BOP employees with the written or verbal order of the Clinical Director or physician designee.

(f) Emergent doses of anti-retroviral medications should only be prescribed for exposed workers in accordance with CDC guidelines. Workers should be informed of the CDC recommendations including but not necessarily limited to the risk, prevention, and drug treatment information included in Appendix 9, HIV Post-exposure Prophylaxis Fact Sheet.

(g) Anti-retroviral medications may have untoward effects, particularly in persons with underlying medical conditions, taking prescribed or over-the-counter medications, and during pregnancy. The provision of emergency doses of HIV anti-retroviral medications to BOP employees must be considered on a case by case basis after a careful discussion of the known risks and benefits of prophylaxis with the employee and whenever possible the direct involvement of the employee’s personal physician. Nonpregnant women of childbearing age who have reason to believe they may be pregnant should be referred for pregnancy testing.

(h) Inmate workers with exposures to blood or OPIM should be evaluated, counseled, and treated with HIV post-exposure prophylaxis when indicated in accordance with CDC guidelines.

(i) Employees and inmate workers with occupational exposures to HIV should have HIV antibodies measured at the time of exposure, and 6 weeks, 12 weeks, and 6 months after the exposure. A 12 month HIV antibody test is considered optional, unless clinically indicated (e.g. history of acute HIV syndrome following an exposure without seroconversion at 6 months). If the source is HIV seronegative, but engaging in behaviors at risk for transmission of HIV infection, follow-up HIV antibody testing at 3 and 6 months should be considered for the exposed employee or inmate worker. HIV testing for employees should be conducted by BOP providers or by community health care providers at the employee's discretion.

2. Documentation/Training

(a) The provision of HIV post-exposure prophylaxis to BOP employees should be documented in the employee's health record or inmate worker's medical record, including the date and description of the exposure, counseling provided, emergency treatment rendered, community provider referral for employees, and a signed informed consent or declination for emergent HIV post-exposure prophylaxis on the Employee Consent/Declination Form for HIV Post-exposure Prophylaxis (Appendix 10) when appropriate.

(b) Specific administrative, personnel, and medical procedures for implementing the CDC guidelines for HIV post-exposure prophylaxis should be outlined in the institution's exposure control plan for bloodborne pathogens. The institution's procedures for providing HIV post-exposure prophylaxis to BOP employees and inmate workers should be included in annual training.

ATTACHMENTS.

Appendix 1. Federal Bureau of Prisons HIV Classification Form

Appendix 2. Medical Evaluation and Treatment of HIV Infection by Immunologic Status

Appendix 3. Anti-retroviral Therapy - Nucleoside Reverse Transcriptase Inhibitors

Appendix 4. Anti-retroviral Therapy - Protease Inhibitors

Appendix 5. Anti-retroviral Therapy - Non-nucleoside Reverse Transcriptase Inhibitors

Appendix 6. Prophylaxis of HIV-Related Opportunistic Infections

Appendix 7. Federal Bureau of Prisons HIV Chronic Care Flowsheet

Appendix 8. HIV Post-exposure Prophylaxis Treatment Guidelines

Appendix 9. HIV Post-exposure Prophylaxis Fact Sheet

Appendix 10. Employee Consent/Declination Form for HIV Post-exposure Prophylaxis

Federal Bureau of Prisons HIV Classification Form

Demographics: Name: (Last) _____ (First) _____ (Middle)_____Reg#: _____
_____ Date of Birth:_____ SSN: _____Race: W B Hispn
Asian Nat. Amer Country of Birth: _____Facility: _____
_____ State: _____

Risk Factors: After 1977 and preceding the first positive HIV antibody test or AIDS diagnosis, the patient had the following risk factors (respond to all categories):

1.	Sex with male	Y	N	Unknown	
2.	Sex with female	Y	N	Unknown	
3.	Injected nonprescription drugs	Y	N	Unknown	
4.	Transfused clotting factor for bleeding disorder	Y	N	Unknown	
5.	Heterosexual relations with any of the following:				
	Injection drug user	Y	N	Unknown	
	Bisexual male	Y	N	Unknown	
	Person with hemophilia/coagulation disorder	Y	N	Unknown	
	Transfusion recipient with documented HIV infection	Y	N	Unknown	
	Transplant recipient with documented HIV infection	Y	N	Unknown	
	Person with HIV infection or AIDS/unknown risk	Y	N	Unknown	
6.	Transfused blood products (other than clotting factor)	Y	N	Unknown	
	product _____ first _____ mo/yr last _____ mo/yr				
7.	Received organ/tissue transplant or artificial insemination	Y	N	Unknown	
8.	Health care worker or clinical laboratory worker	Y	N	Unknown	
9.	Tattoo (while incarcerated)	Y	N	Unknown	

CDC HIV Classification (circle one)

A1	**B1**	**C1**
A2	**B2**	**C2**
A3	**B3**	**C3**

Clinical conditions (Describe clinical status/conditions relevant to A, B, or C classification):

_____

_____

_____

Evaluating clinician: _____ Date: _____

1993 Revised CDC Classification System for HIV Infection

CD4+ T-cells/ µliter	CD4+ (%)	A Asymptomatic	B Symptomatic Disease	C AIDS Indicator Conditions
≥500	≥29%	A1	B1	C1
200-499	14-28	A2	B2	C2
<200	<14	A3	B3	C3
		***** acute (primary) HIV infection *PGL (persistent generalized lymphadenopathy)	Symptomatic conditions that are attributed to HIV infection; or the conditions have a clinical course complicated by HIV. Conditions include but are not limited to the following:: * bacillary angiomatosis * oral candidiasis * vulvovaginal candidiasis (persistent - > 1 month or poorly responsive to tx) * cervical dysplasia (moderate-severe/CIS) * ITP * oral hairy leukoplakia * listeriosis * herpes zoster (involving more than 1 dermatome or 2 separate episodes)	* candidiasis: esophageal * coccidiomycosis: extrapulmonary * cryptococcoses: extrapulmonary * cervical cancer, invasive * cryptosporidiosis: chronic (> 1 month) * CMV retinitis, (or CMV in organs other than liver/spleen/nodes) * HIV encephalopathy * herpes simplex: esophagitis, genital/oral ulcers > 1 month * histoplasmosis: extrapulmonary/disseminated * isosporiasis: chronic diarrhea (> 1 month) * Kaposi sarcoma * lymphoma: Burkitt's, immunoblastic, brain primary * MAC or *M. Kansasii*: extrapulmonary/disseminated * *M. tuberculosis*: pulmonary or extrapulmonary * other mycobacterium: extrapulmonary/disseminated * *Pneumocystis carinii* pneumonia (PCP) * pneumonia (recurrent < 12 months) * progressive multifocal leukoencephalopathy (PML) * salmonella septicemia (> 1 occurrence) * toxoplasmosis (CNS) * wasting syndrome secondary to HIV infection

Category B conditions take precedence over those in Category A; and Category C conditions take precedence over those in Category B.
For classification purposes, the lowest accurate CD4+ T-lymphocyte count or percentage (not necessarily the most recent) should be utilized.

Medical Evaluation and Treatment for HIV Infection by Immunologic Status

Baseline Evaluation:
(1) history/PE including: fundoscopic exam/PAP smear for women (2) dental exam (3) CBC/platelets/CD4+ T-cell count/% (4) plasma HIV RNA
(5) electrolytes/creatinine/LFTS (6) RPR/FTA (review tx history) (7) PPD/symptom review and chest x-ray (8) toxoplasmosis IgG
(9) HBsAg/anti-HCV if LFTs abnormal (10) pneumococcal vaccine (booster at 5 yrs x 1) (11) hepatitis B vaccine if at-risk.

Periodic Evaluation:
(1) CBC/platelet count, LFTs/creatinine/electrolytes - q 3 months on anti-retroviral tx (2) periodic RPR as clinically indicated (3) Pap smear - at 6 months x 1 then annually (repeat if "inadequate", refer to gynecologist for "atypia") (4) influenza vaccination annually (5) other laboratory tests as indicated.

CD4+ T-cells/mm^3	**CD4+ T-cells assessment**	**Viral load**	**Clinician exam**	**Special Evaluations/Treatments**
> 350	q 3-6 months	q 6 months off tx q 3-4 mon. on tx	q 3 months	Observe or initiate anti-retroviral tx depending on viral load Monitor CD4+ T-cell count q 3 months if 350-500 cells/mm^3
200-350	q 3-6 months	q 3-4 months	q 3 months	Initiate anti-retroviral therapy regardless of plasma HIV RNA levels
100-199	q 3-6 months	q 3-4 months	q 2 months	Initiate anti-retroviral therapy regardless of plasma HIV RNA levels Initiate PCP prophylaxis Baseline fundoscopic exam by eye doctor to screen for CMV
50-99	q 3-6 months	q 3-4 months	monthly	Initiate anti-retroviral therapy regardless of plasma HIV RNA levels Initiate toxoplasmosis prophylaxis/Maintain PCP prophylaxis Fundoscopic exam annually by eye doctor to screen for CMV
0-49	q 6 months	q 3-4 months	monthly	Initiate anti-retroviral therapy regardless of plasma HIV RNA levels Maintain PCP/toxoplasmosis prophylaxis Initiate MAC prophylaxis Fundoscopic exam q 6 months by eye doctor to screen for CMV

Plasma HIV RNA should be measured before and 4 weeks after changes in anti-retroviral tx and with evidence of worsening clinical or immune status.
Effect of change in drug therapy on plasma HIV RNA should be evident in 3-4 weeks, but nadir may not be apparent for 2-4 months.
Viral load should not be measured within one month of an acute illness or immunization (due to false elevations).

Medical Evaluation and Treatment for HIV Infection by Immunologic Status

Immune Status	Treatment Options	Comments
Asymptomatic CD4+ T-cells 350/mm^3 **AND** - HIV RNA <20,000 cps/ml (RT-PCR) <10,000 cps/ml (bDNA)	Observe Initiate treatment on case by case basis for inmates with persistent CD4+ T-cell counts between 350-500/mm^3 and low plasma HIV RNA.	Monitor HIV RNA, CD4+ T-cell count, and clinical presentation for disease progression. Inmates with CD4+ T-cells between 350-500/mm^3 must be monitored closely - use low threshold for initiation of antiretroviral therapy. Treatment of asymptomatic patients with CD4+ T-cell counts > 500/mm^3 and low plasma HIV RNA levels is investigational.
Asymptomatic CD4+ T-cells 200-350/mm^3 **OR** HIV RNA: > 20,000 cps/ml (RNA-PCR) > 10,000 cps/ml (bDNA) Regardless of CD4+ count	Treatment per DHHS guidelines (Confirm depressed CD4+ T-cell count with second test before initiating treatment if plasma HIV RNA is < 20,000 cps/ml) (Confirm elevated plasma HIV RNA with second test before initiating first time treatment if CD4+ T-cell count is ≥ 350/mm^3.)	Highly aggressive therapy should be initiated in accordance with current DHHS guidelines. Inmates who fail to attain undetectable plasma HIV RNA after 6 months of therapy should usually be switched to an alternative drug regimen. Dual therapy nucleoside reverse transcriptase inhibitor (AZT/ddI, AZT/ddC, d4T/3TC, AZT/3TC, d4T/ddI) therapy or other suboptimal therapies should be avoided but can be considered for inmates who refuse or are nonadherent to more complicated regimens or have previously been prescribed dual therapy and have brief incarcerations (e.g. presentenced inmates). AZT and d4T are antagonistic and should not be prescribed in combination.. One drug should not be added to a failing regimen, but a single drug can be switched due to drug intolerance to another drug in the same class with a different side effect profile if plasma HIV RNA is undetectable. Monotherapy with any drug is a suboptimal regimen and should always be avoided.
Symptomatic with AIDS or AIDS-related infections; or Asymptomatic with CD4+ T-cell count < 200/mm^3 HIV RNA = any value	Treatment per DHHS guidelines	

Monotherapy with 3TC, non-nucleoside reverse transcriptase inhibitors, or any protease inhibitor is absolutely contraindicated.
Goal of tx is a viral burden < 500 cps/ml (preferably undetectable levels) at 4-6 months predicted by a one log (10 fold) decline in viral burden after one month of tx.

Appendix 3

Anti-retroviral Therapy - Nucleoside Reverse Transcriptase Inhibitors

Anti-retroviral Tx	Dosage	Baseline Labs	Monitoring Labs	Toxicities	Comments
Zidovudine (AZT) Retrovir	200 mg TID or 300 mg BID	CBC/diff	CBC/diff 2,6, and 12 weeks after starting tx. every 3 months if stable	anemia neutropenia myalgia headache insomnia	marrow toxicity with gancyclovir reduce dose for moderate toxicities good CNS penetration
Lamivudine (3TC) Epivir	150 mg BID	none	none	minimal	never prescribe as monotherapy combined with AZT as Combivir
Stavudine (d4T) Zerit	>60kg: 40 mg BID <60kg: 30 mg BID	CBC/diff	CBC/diff	neuropathy	reduce dose for renal disease based on creatinine clearance
Didanosine (ddI) Videx	>60kg:200 mg BID <60kg:125 mg BID; OR, 300-400 mg daily take on empty stomach	CBC/diff amylase liver function	CBC/diff amylase/liver function tests with GI symptoms	diarrhea nausea pancreatitis neuropathy	do not prescribe with history of pancreatitis or hx of alcohol abuse adjust dose in renal/hepatic disease high Na/Mg load
Zalcitabine (ddC) HIVID	0.75 mg TID	CBC/diff	CBC/diff amylase with GI symptoms	neuropathy stomatitis	reduce dose for renal disease
Abacavir	300 mg tabs 300 mg BID	none	none	hypersensitivity reaction (fever, rash, GI sympt.)	drug rechallenge after hypersensitivity reaction may be life threatening

Appendix 4

Anti-retroviral Therapy - Protease Inhibitors

Antiretroviral Tx	Dosage	Baseline Labs	Monitoring Labs	Toxicities	Comments
Nelfinavir Viracept	750 mg TID (250 mg caps) 9 capsules	liver function glucose	liver function glucose at least quarterly	diarrhea	take with light snack or with meals
Indinavir Crixivan	800 mg q 8 h (400 mg caps) 6 capsules	liver function renal function glucose	liver function renal function glucose at least quarterly	kidney stones nausea vomiting	take 1 hr before or 2 hrs after meal/not concurrently with ddI take at least 1.5 liters of water per day dose separately from ddI
Ritonavir Norvir	600 mg BID (100 mg caps) 12 capsules Initiate low dose then escalate to reduce GI effects	liver function glucose	liver function renal function glucose at least quarterly	nausea vomiting paresthesias	take with food store in refrigerator many drug interactions: review all meds before prescribing
Saquinavir Fortovase	1200 mg TID (200 mg caps) 18 capsules	liver function glucose	liver function glucose at least quarterly	diarrhea nausea	take with full meal Fortovase 400 mg BID when given with Ritonavir 400 mg BID

Never prescribe protease inhibitor (PI) as a single anti-retroviral agent. Compliance with PI therapy is essential to avoid the rapid development of resistance.
Dose escalation for ritonavir: 300 mg BID (day 1-2); 400 mg BID (day 3-5); 500 mg BID (day 6-13); then 600 mg BID.
Protease inhibitors may have serious interactions with certain drugs metabolized by the liver, e.g. astemizole, cisapride; review drug interactions carefully.

Appendix 5

Anti-retroviral Therapy - Non-nucleoside Reverse Transcriptase Inhibitors

Anti-retroviral Tx	Dosage	Baseline Labs	Monitoring Labs	Toxicities	Comments
Nevirapine Viramune	200 mg tabs - daily for 14 days, then if tolerated advance to standard tx. 200 mg BID	CBC liver function tests	liver function tests quarterly	rash	incidence of rash reduced by gradual dose escalation whenever drug is stopped; restart at 200 mg daily for 14 day lead in period <u>decreases</u> levels of some protease inhibitors;
Delavirdine Rescriptor	400 mg TID (100 mg tabs) no dose escalation required	CBC liver function tests	CBC liver function tests quarterly	rash neutropenia with nelfinavir	<u>increases</u> levels of protease inhibitors, but no dosage adjustment of PI is required except for indinavir (reduce to 600 mg q 8 hrs.) multiple drug interactions: review all drugs, serious toxicities with cisapride, terfenadine, astemizole; absorption decreased with antacids; administer separately from ddI.
Efavirenz Sustiva	600 mg daily (200 mg caps)	CBC liver function tests	CBC liver function tests quarterly	dizziness "disconnected feeling" rash - mild possible fetal anomalies	extremely potent antiviral effect CNS effects may resolve with treatment not recommended for pregnant women drug interactions being evaluated; review current data

Non-nucleoside analogues should never be prescribed as monotherapy or in combination with one another.

Appendix 6

Prophylaxis of HIV-Related Opportunistic Infections

Pathogen	Drug	Dosage	Toxicities	Comments
Pneumocystis carinii	TMP-SMX	1 SS/day **(1st choice)** 1 DS/day 1 DS 3x/week	rash/fever/nausea leukopenia/hepatitis	prevents toxo and bacterial infections monitor CBC q 3 months
Indications: (1) CD4+ ct <200 cells/mm^3 (2) prior PCP (3) oral candidiasis	Dapsone	100 mg/day	hemolysis/hepatic methemoglobinemia	screen for G-6-PD deficiency
	Pentamidine	300 mg q month aerosolized (administer by Respirgard II nebulizer)	bronchospasm/cough (responds to bronchodilator tx)	obtain screening chest x-ray for TB
Toxoplasmosis gondii	TMP-SMX	1 DS/day **(1st choice)** 1 SS/day	rash/fever/nausea leukopenia/hepatitis	repeat toxo IgG if previously negative when CD4+ T-cells < 100/mm^3
Indication: Toxo IgG+ and CD4+ ct <100 cells/mm^3	Dapsone + Pyrimethamine + Leukovorin	50 mg/day 50 mg/week 25 mg/week	hemolysis/anemia	monitor for anemia/leukopenia with either regimen - CBC at least q 3 months
Mycobacterium avium *	Azithromycin	1200 mg/week **(1st choice)**	nausea/vomiting	
Indication: CD4+ ct < 50 cells/mm^3	Clarithromycin	500 mg BID	nausea/vomiting	review drug interactions/do not give with terfenadine or astemizole
*R/O disseminated MAC infection with blood culture before giving prophylaxis	Rifabutin	300 mg/day	uveitis, arthralgias hepatitis	uveitis when given with fluconazole creates rifampin resistance review drug interactions

Routine prophylaxis for fungal infections is not indicated.
Routine prophylaxis for CMV infection is not indicated: Screen routinely for retinitis.
Maintain prophylaxis for opportunistic infections once initiated, despite evaluations in CD4+ T-cell counts.

Appendix 7

Federal Bureau of Prisons HIV Chronic Care Flowsheet

Demographics Name: (Last) _____ (First) _____ REG#: _____Age:____ Gender: M F Race: W B Asian Hispan Nat American BOP Facility: _____

History Date of Initial Dx: __/__/__ Location: _____AIDS-defining illnesses: _____Prior Anti-retroviral tx: _____ _____PPD: ____ mm. PPD Date: __/__/__ Chest x-ray: Normal Abnormal Date: __/__/__
RPR/FTA: ____ RPR Date: __/__/__ Tx: _____ Tx date(s) _____Pneumovax: Y N Date: __/__/__ Toxo IgG: _____ Drug Allergies: _____

Periodic Eval.	Date / /	Date / /	Date / /	Date / /	Date / /	Date / /
CDC Class.						
CD4 count/CD4%						
Viral Load						
WBC/HCT						
Ophthalmology						
Pap/Gyn						
Other						
Anti-Retrov Tx						
Prophylaxis						
AIDS Conditions Hospitalizations						
Follow-up						
Signature						

HIV Occupational Post-exposure Prophylaxis (PEP)*

Exposure	Severity Factor	Source Status			Counsel	Treatment Regimen
		(+) titer		Unk		
		low	*high*		(Based on any	*one X)*
Percutaneous	**more severe**	**X**	**X**		**Recommend**	**ZDV + 3TC + (*IDV* or *NFV*)**
	less severe *or* large volume		**X**		**Recommend**	**ZDV + 3TC + (*IDV* or *NFV*)**
	less severe *or* large volume	**X**			**Recommend**	**ZDV + 3TC**
	***any* factor above**			**X**	**Consider**	**ZDV + 3TC**
Mucous Membrane *(or compromised skin)*	**large volume**		**X**		**Recommend**	**ZDV + 3TC + (*IDV* or *NFV*)**
		X			**Recommend**	**ZDV + 3TC**
				X	**Consider**	**ZDV + 3TC**
	small volume		**X**		**Consider**	**ZDV + 3TC**
		X		**X**	**PEP may**	***NOT* be warranted**
Skin *(intact skin)*	**higher volume or prolonged time**		**X**		**Recommend**	**ZDV + 3TC + (*IDV* or *NFV*)**
		X			**Recommend**	**ZDV + 3TC**
				X	**Consider**	**ZDV + 3TC**
	other	**X**	**X**	**X**	**PEP may**	***NOT* be warranted**

NOTE: NO PEP NEEDED - once source is <u>identified as HIV seronegative</u> without symptoms of HIV infection, evidence of AIDS or clinical history of acute HIV syndrome, or evidence of recent high risk exposure to HIV infection. For cases involving exposures to HIV seronegative sources with symptoms of HIV infection or high-risk inmates who refuse HIV testing, PEP should be continued in accordance with CDC recommendations for exposures to sources with unknown HIV serostatus.

***Also refer to CDC algorithms for HIV PEP, *MMWR* , Vol. 47/No. RR-7, May 15, 1998**

HIV Post-exposure Prophylaxis - Definitions*

EXPOSURE

(1) *Percutaneous:* is a needlestick or other sharp object penetration.
(2) *Mucous membrane*: eyes, nose, ear, mouth or compromised skin integrity (chapped, dermatitis, abrasion, wound).
(3) *Skin*: is intact skin only with higher volume of blood or prolonged contact time.

SEVERITY FACTOR

(1) *More severe: a* large-bore hollow needle, deep puncture, visible blood on device, needle in source patient's artery or vein.
(2) *Less severe* is solid needle or superficial scratch.
(3) *Large volume* is several drops, major blood splash and/or longer duration (i.e. several or more minutes).
(4) *Small volume* is a few drops, short duration.

SOURCE STATUS

(1) (+) *Positive titer/HIV infected:* (+) lab for HIV antibody or HIV RNA, or physician-diagnosed AIDS.
   a. *High titer* means advanced AIDS, primary HIV infection, high or increasing viral load or low CD4 count.
   b. *Low titer* means asymptomatic and high CD4 count.
(2) Unk, *Unknown*: means the source status is unknown or unconfirmed.
(3) (-) *Negative*: lab documentation (-) HIV antibody, (-) PCR for HIV RNA, or HIV p24 collected at or near the time of exposure and no recent retroviral- illness.

COUNSEL

(1) *Recommend* means the exposure represents an increased risk and use of PEP is appropriate.
(2) *Consider* means the exposure poses a negligible risk and use of PEP depends on whether the risk for drug toxicity outweighs the benefit of PEP decided by the exposed HCW and the clinician.
(3) *PEP may not be warranted* means the exposure type does not pose known risk. PEP is based on whether the risk for drug toxicity outweighs the benefit of PEP decided by the exposed HCW and the clinician.

TREATMENT

(1) *Basic two-drug regimen* is four weeks of Zidovudine (ZDV), 600 mg per day in two or three divided doses, and lamivudine (3TC), 150 mg twice daily, given orally.
(2) *Expanded three-drug regimen* is the basic regimen plus either indinavir (IDV), 800 mg every 8 hours, or nelfinavir (NFV), 750 mg three times a day, given orally.
(3) The optimal duration of drug therapy is unknown, but four weeks of HIV PEP is recommended.

(Treatment regimens remain relatively unstudied with the exception of ZDV. Drug toxicity monitoring should include a CBC and renal and hepatic function tests at baseline and 2 weeks after starting PEP).

*Adapted from CDC guidelines: *MMWR*, Vol 45/No. 22, June 7, 1996 *and* Vol 47/No. RR-7, May 15, 1998.

HIV Post-Exposure Prophylaxis Fact Sheet

Question #1 - What is my risk of acquiring HIV infection following an exposure?

Answer: The risk of acquiring HIV infection is related to the type and severity of exposure to blood or other potentially infectious body fluids that include: semen, cerebrospinal fluid, pleural fluid, peritoneal fluid, vaginal secretions, pericardial fluid and amniotic fluid. The average risk of acquiring HIV infection following an exposure from a puncture or cut in the skin is 0.3% (3 out of 1,000). The risk increases with the depth of the injury, if visible blood was present on the device causing the injury, if the device was previously in a patient's vein or artery, or if the source of the exposure was a person with AIDS. The risk of acquiring HIV infection after the exposure of mucous membranes of the eyes, nose, or mouth to HIV-infected material is 0.1% (1 out of a thousand). The risk of acquiring HIV infection after the exposure of intact skin to HIV-infected material is < 0.1% (The risk may be increased if the skin is not intact, or there is prolonged exposure with a large amount of blood). Every potential exposure should be discussed with a physician so that the specific risks of the particular exposure can be reviewed and assessed.

Question #2 - If I acquire HIV infection, can I be cured?

Answer: Presently there is no cure for HIV infection. Nearly all persons infected with HIV develop the acquired immunodeficiency syndrome (AIDS). Current treatments for HIV infection prolong life and significantly delay the progression of infection to AIDS, but have not be proven to completely eradicate HIV. Prevention of HIV infection is critical.

Question #3 - If I have been exposed to HIV, what can I do to prevent infection?

Answer: Studies of health care workers exposed to HIV indicate that the medication, zidovudine (AZT), can reduce the transmission of HIV infection following an occupational exposure by nearly 80%. The Centers for Disease Control (CDC) currently recommends that persons at risk for acquiring HIV infection through occupational exposure to blood or other potentially infectious fluids be recommended or considered for treatment with 2 or 3 drugs effective against HIV for a one month period. The medications should be initiated as soon as possible following an exposure, preferably within 2 hours. The determination that prophylactic treatment should be recommended, considered, or may not be warranted is based on the type of exposure and the HIV status and condition of the source of the exposure.

Question #4 - If I have been exposed to urine, feces, or saliva from a person with HIV infection or AIDS should I take prophylactic medication?

Answer: The CDC does not recommend prophylactic treatment for HIV infection following occupational exposure to urine, feces, or saliva unless these substances are visibly contaminated with blood.

Question #5 - Do the preventive medications have harmful side effects?

Answer: The toxicities of the drugs used to prevent HIV infection are largely unknown in persons without HIV infection. The drugs do have significant side effects that have been documented primarily in persons with HIV infection (see below). Drug toxicities can be significantly exacerbated by drug interactions. If you are currently taking prescribed medications for other health reasons you should review potential drug interactions and toxicities with your physician prior to taking preventive medications for HIV. Pregnancy itself should not preclude post-exposure prophylaxis, however, the known and unknown potential toxicities of antiretroviral medications on the mother, fetus, and newborn child should be discussed carefully with your physician. Pregnancy testing is recommended if you are of childbearing age of unknown pregnancy status and have reason to believe you may be pregnant. When feasible, pregnant or potentially pregnant employees experiencing an exposure to HIV, should consult with their obstetrician or other personal physician when considering HIV post-exposure prophylaxis. Zidovudine (AZT) use in the second and third trimesters of pregnancy and early infancy, to date, has not been associated with serious adverse effects for the mother or her infant. Information on the safety of zidovudine (AZT) during the first trimester or other antiretroviral medications during any stage of pregnancy is limited.

Prophylactic Anti-retroviral Medications:

Zidovudine (Retrovir) (AZT) - headache, muscle pains, nausea, sleeping problems, anemia
Lamivudine (Epivir) (3TC) - minimal symptoms
Indinavir (Crixivan) - nausea, vomiting, diarrhea, kidney stones; (take on empty stomach or with light snack and drink six 8 oz. glasses of water every day)
Nelfinavir (Viracept) - diarrhea, nausea (take with meals)

Question #6 - How will I know if I have been infected or protected from infection with HIV?

Answer: Your physician should measure your blood for HIV antibodies at the time of exposure, at 6 weeks, 12 weeks, and at 6 months. If you do not develop HIV antibodies by 6 months you are most likely not infected with HIV. In certain cases, your physician may measure HIV antibodies at 12 months as an extra precaution.

Question # 7 - Do I need to take any precautions during the 6 months I am awaiting confirmation that I have not newly acquired HIV infection?

Answer: Yes. You should follow these recommendations and maintain these precautions until advised that they are no longer necessary by your physician:

1. Report any unusual symptoms to your physician including fever, swollen glands, or rash.

2. Avoid exposing others to your blood or other potentially infectious body fluids. Use condoms during sexual intercourse. Do not share needles, razors, toothbrushes or other items that may be contaminated with your blood.

3. Use birth control measures to prevent pregnancy.

4. Do not donate blood, sperm, or other potentially infectious body substances.

Appendix 10

Federal Bureau of Prisons
Employee Consent/Declination Form for HIV Post-Exposure Prophylaxis

I, _____ have been counseled on the risks of transmission of HIV infection following an exposure incident while working as a BOP employee. I have also been educated on the benefits and the potential side effects and drug toxicities related to post-exposure prophylaxis with anti-retroviral medications. I understand that post exposure prophylaxis is not a guarantee against HIV infection, but has been reported by the Centers for Disease Control to be effective in reducing HIV transmission following certain exposures.

Consent

I have chosen to take an emergency dose(s) of anti-retroviral prophylactic medication.

_____ _____
Employee Signature Date

_____ _____
Witness (counseling health care provider) Date

Declination

I have chosen not to take an emergency dose(s) of anti-retroviral prophylactic medication.

_____ _____
Employee Signature Date

_____ _____
Witness (counseling health care provider) Date

NOTE: Zidovudine (AZT) use in the second and third trimesters of pregnancy and early infancy, to date, has not been associated with serious adverse effects for the mother or her infant. Information on the safety of zidovudine during the first trimester or other anti-retroviral medications during any stage of pregnancy is very limited. Nonpregnant employees of childbearing age who may be pregnant should be tested for pregnancy. Pregnancy itself should not necessarily preclude HIV post-exposure prophylaxis, however, pregnant employees experiencing an exposure to HIV, should consult with their physician and consider both the known and unknown risks and benefits related to treatment.

FEDERAL BUREAU OF PRISONS TREATMENT GUIDELINES FOR TUBERCULOSIS DISEASE

PURPOSE. The Federal BOP Treatment Guidelines for Tuberculosis Disease define a standard of care for the medical management of tuberculosis (TB) to ensure that BOP inmates diagnosed with active TB receive effective therapy, while limiting the development of resistant disease and reducing contagion.

REFERENCES.

Prevention and Control of Tuberculosis in Correctional Facilities, Recommendations of the Advisory Council for the Elimination of Tuberculosis, MMWR Vol. 45/No. RR-8, June 7, 1996, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta, Georgia.

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Prevention and Treatment of Tuberculosis Among Patients Infected with Human Immunodeficiency Virus: Principles of Therapy and Revised Recommendations, *MMWR*, Vol. 47, No. RR-20, October 30, 1998, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta, Georgia.

DEFINITIONS.

Acid-fast bacilli (AFB) are bacteria that retain certain dyes after being washed in an acid solution. Most acid-fast bacilli are mycobacteria. When AFB are seen on a stained smear of sputum or other clinical specimen, a diagnosis of TB should be suspected; however, the diagnosis of TB is not confirmed until a culture is grown and identified as *M. tuberculosis*.

Culture is the process of growing bacteria in the laboratory so that organisms can be identified.

Directly observed therapy (DOT) is the unit dose administration of medications to a patient by a trained health care provider.

Drug susceptibility tests are the laboratory tests that determine whether the TB bacteria cultured from a patient are

susceptible or resistant to various anti-tuberculosis drugs.

Multi-drug resistant tuberculosis (MDR-TB) is active TB caused by *M. tuberculosis* organisms that are resistant to more than one anti-tuberculosis drug; in practice, often refers to organisms that are resistant to both isoniazid and rifampin with or without resistance to other drugs.

Mycobacterium tuberculosis is the mycobacterial species that is the primary cause of active TB disease in the United States.

Negative Pressure Isolation Room (NPIR) is a room designated for the isolation of patients with contagious tuberculosis disease that has adequate directional airflow, air exchanges, and exhaust that reduce transmission of *M. tuberculosis*, in accordance Centers for Disease Control guidelines.

Smear (AFB smear) is the laboratory technique for visualizing mycobacteria. The specimen is smeared onto a slide and stained, then examined using a microscope. A large number of mycobacteria seen on an AFB smear from a person with TB usually indicates infectiousness. However, a positive smear is not diagnostic of TB, because organisms other than *M. tuberculosis* may be seen on an AFB-smear.

PROCEDURES.

a. Diagnosis

The expedient diagnosis of inmates with active contagious TB is critical for providing effective treatment and for preventing the transmission of *M. tuberculosis* to staff and other inmates. Inmates should be screened by symptom review, tuberculin skin testing, and chest radiographs in accordance with BOP policy so that TB disease is detected as soon as possible. Although the majority of inmates with active TB disease are symptomatic with positive tuberculin skin tests and characteristic abnormal chest radiographs, correctional health care providers should always maintain a high index of diagnostic suspicion for TB and be alerted to the following exceptions:

1. Inmates with active TB disease may have negative (0 millimeter) tuberculin skin test measurements, particularly when immunocompromised.

2. Inmates with active TB disease may have completely normal or mildly abnormal chest radiographs, particularly with HIV co-infection.

3. Atypical presentations of active TB disease are common with HIV co-infection and can occur concurrently with other respiratory infections.

4. Inmates with active TB disease may be relatively healthy appearing and deny symptoms.

5. TB can occur in nearly any organ of the body and should always be considered when an inmate presents with a fever or infection of unknown etiology that does not respond to routine antibiotic treatments.

b. Treatment

All BOP inmates with the clinical or laboratory diagnosis of TB disease should be considered candidates for four drug anti-tuberculosis initial drug therapy in accordance with the treatment guidelines enumerated in Appendix 1 (Federal Bureau of Prisons Treatment Guidelines for Tuberculosis Disease) adapted from Centers for Disease Control recommendations.

1. Since inmates may have resistance to one or more TB drugs at baseline, the initial prescription of four-drug therapy is essential for minimizing the development of further drug resistance. Four drug therapy also hastens the conversion of AFB smears from positive to negative; thus reducing infectiousness. In certain cases in which MDR-TB is suspected, alternative treatments with four or more drugs may be indicated in consultation with a TB expert and the local health department.

2. TB treatment regimens may require adjustments once drug susceptibility tests become available. Any deviations to the standard regimen are rarely indicated and should always be in accordance with the following caveats:

(a) Never treat active TB with a single drug.

(b) Never add a single drug to a failing tuberculosis treatment regimen.

(c) Never switch to a two drug regimen of isoniazid and rifampin before drug sensitivities confirm non-resistant TB.

3. All TB medications should be administered by directly observed therapy (DOT) to ensure adherence to the prescribed treatment regimen and reduce the emergence of resistant disease.

4. All TB medications should be prescribed according to the inmate's weight and adjusted appropriately with weight changes.

5. Clinical improvement following empiric treatment for pulmonary TB with negative cultures is strongly suggestive of culture-negative pulmonary TB. Medications should be continued. If the clinical response to treatment is satisfactory, an abbreviated treatment course may be prescribed in accordance with

Appendix 1.

6. Extrapulmonary TB is generally treated using the same drug regimens as pulmonary tuberculosis, although TB osteomyelitis, lymphadenitis, and meningitis frequently require extended courses of treatment. Serial bacteriologic evaluations may be limited by disease location; therefore the response to treatment must be judged on the basis of clinical, and where applicable, radiologic findings.

7. TB disease complicated by HIV co-infection is treated with the same treatment regimens as TB without HIV infection, for those inmates who are not receiving antiretroviral drug therapy or are not prescribed protease inhibitors or nonnucleoside reverse transcriptase inhibitors. Rifampin is contraindicated in combination with protease inhibitors or non-nucleoside reverse transcriptase inhibitors, so an alternative non-standard TB treatment regimen must be used. Since alternative, effective, non-rifampin containing antituberculosis regimens are available, antiretroviral therapy should not be discontinued so that a rifampin-containing regimen can be prescribed.

Rifabutin (150 mg daily) and (5 mg/kg - 300 mg maximum dose, twice weekly) may be substituted for rifampin for treating TB for inmates prescribed indinavir and nelfinavir, but is contraindicated with ritonavir, hard-gel saquinavir, and delavirdine. Data on the interactions of rifabutin with other protease inhibitors and nonnucleoside reverse transcriptase inhibitors are limited. Rifabutin toxicity may result when prescribed with antiretroviral agents; monitor closely for arthralgias, symptoms of uveitis, leukopenia, and liver dysfunction. Dosage adjustments in antiretroviral medications may be indicated when using rifabutin. For inmates with contraindications to rifabutin, an alternative treatment option should be considered.

All inmates with active TB and HIV co-infection should be treated and monitored in consultation with an expert in treating HIV infection and TB, using current CDC guidelines. Although persons with TB and HIV infection usually respond adequately to anti-tuberculosis therapy, drug side effects are more frequent and bacteriologic response may be less sustained, necessitating careful monitoring and if necessary, an extended treatment course.

TB disease and its associated systemic symptoms may be paradoxically exacerbated when persons with HIV co-infection are simultaneously treated with highly effective antiretroviral regimens, resulting in immune reconstitution with increased T-lymphocytes and enhanced cytotoxic activity against *M. tuberculosis*. Changes in antituberculosis or antiretroviral therapy are rarely necessary in persons with paradoxical

reactions. For persons with severe reactions, one option, is to continue with appropriate antituberculosis therapy and administer a short course of steroids to suppress the enhanced immune response.

8. A physician consultant with TB treatment expertise and the local health department should be consulted for any of the following TB cases:

(a) A treated case of TB that does not result in negative cultures following two months of therapy.

(b) All cases of drug intolerance, pregnancy, or other situations requiring deviation from a standard treatment regimen.

(c) All cases of multi-drug resistance.

c. Containment

1. Inmates diagnosed with active smear-positive pulmonary TB should be assigned to a NPIR in a community hospital or BOP medical referral center until no longer contagious in accordance with BOP policy and the following parameters:

(a) Treatment with a four drug regimen per treatment guidelines or other equally effective regimen for at least two weeks.

(b) Clinical evidence of improvement.

(c) Conversion of three (3) morning sputum smears to negative.

(d) If drug resistance is suspected, documentation of drug sensitivities and clinical evidence of effective therapy.

2. If AFB smears are negative, but TB is suspected based on the clinical presentation and chest radiograph findings, the inmate should be housed in a NPIR during initial diagnosis and treatment and not released until clinically improving and considered no longer contagious by the treating physician. The inmate should be maintained on TB treatment until sputum or bronchial washing culture results are available, at which time the need for continued treatment should be reassessed.

d. Monitoring Treatment

All inmates should be monitored at least monthly by a physician to evaluate the clinical response to therapy and monitor side effects to medications. Baseline laboratory

studies, TB medication regimens, and monitoring of adverse reactions should be in accordance with the parameters outlined in Appendix 1 and the following guidelines:

1. Inmates with sputum cultures positive for *M. tuberculosis* should have three (3) adequate morning sputum cultures obtained monthly until sputum cultures convert to negative. Inmates who can not voluntarily provide a sputum sample at a BOP facility should be sent to an appropriate community health care facility for sputum induction. A final sputum culture should be obtained at the completion of successful treatment as a reference culture.

2. Sputum cultures positive for *M. tuberculosis* after two months of drug treatment are suggestive of ineffective therapy. Repeat drug sensitivities should be obtained to evaluate for resistant disease. Inmates with TB disease who do not respond to standard drug therapy by two months of treatment may be nonadherent to their medication regimen or may have malabsorption, drug interactions, or other problems resulting in subtherapeutic serum drug levels. Persons with chronic gastrointestinal disease (e.g. Crohns disease, HIV-related diarrhea) are particularly at risk for drug treatment failure. Serum drug levels should be obtained to document the adequacy of medication delivery for inmates with known malabsorption or who fail to respond to TB treatment.

3. Liver function studies should be obtained at baseline. If baseline liver enzymes are elevated, inmates should be screened for HBV and HCV infections. Inmates with elevations in liver enzymes greater than 3-5 times normal are at higher risk for hepatotoxicity from isoniazid and other potentially hepatotoxic TB medications. Elevations in liver enzymes are not necessarily a contraindication to treatment, but consultation with a TB expert is recommended. Monthly monitoring of liver enzymes should be considered for the following conditions:

(a) Persons with baseline liver enzymes greater than normal.

(b) Persons 35 years of age or older.

(c) Persons with chronic liver disease from alcohol, viral hepatitis or other etiologies.

(d) Persons prescribed other potentially hepatotoxic drugs.

(e) Persons with a history of previous adverse reactions to isoniazid.

(f) Pregnant women.

4. Visual acuity and red-green color vision should be assessed at baseline and monthly thereafter for inmates treated with ethambutol. Optometry or ophthalmology evaluations are indicated at three months of treatment and every three months thereafter while inmates are receiving ethambutol.

5. Baseline and monthly creatinine/audiograms are indicated for inmates receiving streptomycin or other aminoglycosides.

6. Chest radiographs should be obtained at baseline, at the completion of therapy, and during treatment when clinically indicated.

e. Contact Investigations

All TB cases should be investigated to assess the contagiousness of the index case and to determine if inmate, staff, or other contacts should be evaluated and/or notified. Extrapulmonary and AFB-smear negative TB cases, usually do not require a contact investigation, although this should be determined on a case by case basis. Contact investigations should be conducted in consultation with the local health department and Regional and Central Office administrative staff in accordance with the following guidelines:

1. Contact investigations should be initiated by evaluating the closest inmate and staff contacts of the index case.

2. All inmate contacts should have a medical record review and personal interview for symptoms of active TB. Symptomatic inmates should receive a chest radiograph and complete medical evaluation by a physician regardless of tuberculin skin test status and should be isolated in a NPIR if contagious TB is suspected by chest radiograph or clinical findings. All other asymptomatic inmate contacts do not require isolation.

3. Mandatory tuberculin skin testing of all previously skin-test negative inmate contacts should be conducted at baseline (unless previously tested with 1-3 months of exposure) and repeated 10-12 weeks from the last contact with the source case to assess transmission of new TB infection. Contacts with tuberculin skin test readings of 5 millimeters or greater should be prescribed TB prophylaxis unless medically contraindicated.

4. Immunocompetent inmate contacts with past histories of positive tuberculin skin tests should not be skin-tested, but should be interviewed for symptoms of active TB and should receive a chest radiograph if symptomatic.

5. Inmate contacts with HIV infection or other serious immunocompromised conditions should receive chest radiographs regardless of skin-test status. Very close immunocompromised

contacts, such as cell mates, should be prescribed prophylaxis regardless of tuberculin skin test results.

6. If inmate contacts refuse medically indicated isoniazid prophylaxis they must be monitored by chest radiographs every six months for two years if HIV seronegative; and every six months indefinitely if HIV seropositive.

7. All staff contacts, regardless of previous tuberculin skin test results, should be interviewed for symptoms of active TB disease. Staff should be counseled about the medical conditions that increase the risk of TB, and if such conditions exist, staff should be referred to their physician for further evaluation regardless of TB skin-test history.

8. Tuberculin skin testing should be offered to all previously skin test-negative staff contacts as a baseline (unless staff were tested in the previous 1-3 months) and then repeated 10-12 weeks from the last contact with the source case to assess transmission of new TB infection. Staff contacts with tuberculin skin test measurements of 5 millimeters or greater should be referred to their physician for further medical evaluation.

9. Tuberculin skin testing is not indicated for staff contacts with previously measured positive tests.

10. If the initial contact investigation indicates that significant transmission of TB infection has occurred to other inmates or correctional staff, the contact investigation should be expanded to include evaluation of contacts who had less immediate contact with the index case.

ATTACHMENTS.

Appendix 1. Federal Bureau of Prisons Tuberculosis Treatment Guidelines

Federal Bureau of Prisons Tuberculosis Treatment Guidelines

Diagnostic Category	Length of Regimen	Initial Phase INH/RIF/PZA/EMB (or SM) for 8 weeks (daily for 2 weeks, then biweekly for 6 weeks)		CONTINUATION PHASE INH/RIF for 16 weeks (2 OPTIONS)		MONITORING PARAMETERS
Adults - TB **Culture positive - pulmonary or extrapulmonary**	**6 months minimum** **Longer treatment may be required for TB meningitis or bone/joint TB**	**DAILY DOSE (MAXIMUM DOSE)** **Daily dose x 14 doses** **INH 5 mg/kg (300 mg/day)** **RIF 10 mg/kg (600 mg/day)** **PZA 15-30 mg/kg (2g/day)** **EMB 15-25 mg/kg** **or** **SM 15 mg/kg ≤60 yr. (1.0 g/day)** **SM 10 mg/kg if >60 yr. Old (750 mg - 1 g)** **Note: EMB should be started at 15 mg/kg to reduce the risk of ocular toxicity. The use of 25 mg/kg should be reserved for patients requiring retreatment, or treatment of drug resistant TB.**	**TWICE WEEKLY DOSE (MAXIMUM DOSE)** **Twice weekly x 6 weeks.** **INH 15 mg/kg (900 mg/dose)** **RIF 10 mg/kg (600 mg/dose)** **PZA 50-70 mg/kg (4g/dose)** **EMB 50 mg/kg/dose** **or** **SM 25-30 mg/kg ≤60 yr. (1.5 g/dose)** **SM 750 mg - 1 g if >60 yrs)** **Note: Pyridoxine - 50 mg/day should be given concurrently with INH to prevent INH-associated peripheral neuropathy.** **Drugs prescribed twice weekly should be administered 2 or 3 days apart.**	**DAILY DOSE (MAXIMUM DOSE)** **INH 5 mg/kg (300 mg/day)** **RIF 10 mg/kg (600 mg/day)** **Note: AFTER 8 WEEKS OF 4 DRUG THERAPY NEVER SWITCH TO 2 DRUG THERAPY UNTIL SUSCEPTIBILITY TO INH AND RIF HAS BEEN DEMONSTRATED.**	**TWICE WEEKLY DOSE (MAXIMUM DOSE)** **INH 15 mg/kg (900 mg/dose)** **RIF 10 mg/kg (600 mg/dose)** **Note: Drugs prescribed twice weekly should be administered 2 or 3 days apart.**	**Baseline: Chest x-ray, morning sputums for AFB X 3, CBC, platelet count, creatinine, uric acid, bilirubin, hepatic enzymes, visual acuity/red-green color perception(EMB), and audiogram(SM).** **Do susceptibility drug testing with first sputum cultures and as needed.** **Ongoing: Monthly evaluation by a physician for symptoms and targeted exam** **LFTs monthly if elevated at baseline Creatinine/audiogram monthly on SM** **Visual acuity/red-green color vision monthly, eye doctor evaluation every 3 months while on EMB** **Certain high-risk groups, may have increased propensity for INH-induced hepatitis and require monthly liver enzymes. Presence of hepatitis does not preclude treatment for TB--patient must be monitored closely. Other labs at discretion of physician.** **Obtain 3 consecutive daily sputums for smear and culture every month until conversion. Repeat drug susceptibility testing if patient fails to respond clinically or remains culture positive after 2 months. Chest x-ray, sputum smear and culture at end of treatment for future comparisons.**
Adults - **Pulmonary with negative smear and culture. Patient is symptomatic.**	**4 months minimum** **6 months if HIV infected.**	**INITIAL PHASE INH/RIF/PZA/EMB (or SM) for 8 weeks**		**CONTINUATION PHASE INH/RIF for 8 weeks**		**Same as above** **Chest x-ray at 3 months. Failure of x-ray to respond to treatment within 3 months suggestive of previous (not current) TB or another disease.**
		Same as above	**Same as above**	**Doses same as above. Continue EMB and PZA if drug resistance likely.**	**Doses same as above. Continue EMB and PZA if drug resistance likely.**	

INH-isoniazid, RIF-rifampin, PZA-pyrazinamide, EMB-ethambutol, SM-streptomycin. Adjust dosages as weight. changes. Medicines must be given by directly observed therapy.

FEDERAL BUREAU OF PRISONS TUBERCULOSIS TREATMENT GUIDELINES - SPECIAL CONSIDERATIONS

DIAGNOSTIC CATEGORY	REGIMEN	MEDICATIONS	MONITORING PARAMETERS
Pregnancy	**9 months minimum. Treatment should begin as soon as TB is suspected.**	**Treat with appropriate doses of INH/RIF/EMB. Do not use PZA unless dealing with drug-resistant disease with no alternatives. Inadequate tetratogenicity data for PZA** **Give Pyridoxine (B6) 50 mg/day concurrently.** **SM has documented harmful effects on the fetus and should not be used.** **Discontinue EMB once INH/RIF sensitivity results are documented.** **Consult with an infectious disease expert for appropriate treatment regimen**	**Baseline: Chest x-ray, morning sputums for AFB X 3, CBC, platelet count, serum creatinine, uric acid, liver enzymes, visual acuity, and red-green color vision.** **Ongoing: Monthly symptom review and exam by clinician. Assess visual acuity/ red-green color perception monthly and eye doctor evaluation every 3 months while on EMB. With hepatic disease, renal disease or gout obtain monthly liver function tests, creatinine, or uric acid respectively. Certain high-risk groups for isoniazid-induced hepatitis require monthly liver enzymes. Presence of hepatitis does not preclude treatment for TB. Patient must be monitored closely. Other laboratory studies at the discretion of the physician.** **Obtain 3 consecutive daily sputums every month until conversion. Do susceptibility drug testing with first cultures and as needed. Repeat drug susceptibilities if patient fails to respond clinically or remains culture positive after 2 months.** **Chest x-ray, sputum smear and culture at end of treatment and more frequently as indicated. If pregnant woman is HIV positive or has drug resistant TB, consult infectious disease consultant.**
HIV Infection	**Standard 6 month regimen, unless patient on certain antiretroviral drugs - then consult CDC guidelines and TB expert for treatment recommendations**	**Treatment may need to be prolonged due to adverse drug reactions or poor drug absorption. RIF contraindicated with protease inhibitors and nonnucleoside reverse transcriptase inhibitors.**	**Adverse reactions more common. Monitoring same as for adult standard. If rifabutin prescribed, monitor for uveitis, arthralgia, and leukopenia. If there is no culture conversion at the end of 2 months, reevaluate patient and repeat drug susceptibility tests. Treatment should be prolonged with any evidence of suboptimal response with therapy.**
INH Resistance/ Intolerance	**6 months of 4-drug standard regimen effective. After INH resistance/intolerance identified, discontinue INH. Tx with RIF/ PZA/EMB for duration of therapy given twice weekly.**	**Same as adult standard excluding INH from regimen.**	**Same as adult standard. Monitor cultures and drug sensitivities closely.**
INH/Rifampin resistance (MDR-TB)	**Continue treatment until bacteriologic sputum conversion followed by 12-24 months of at least 3 drug treatment.**	**Give at least three new drugs to which the organism is susceptible.** **Consult with tuberculosis expert to ensure effective medical management.**	**Same as adult and children standards with monthly monitoring of cultures and drug sensitivities until conversion.**

INH-isoniazid, RIF-rifampin, PZA-pyrazinamide, EMB-ethambutol, SM-streptomycin. Adjust dosages as weight changes. Administer all medicines by directly observed therapy.

FEDERAL BUREAU OF PRISONS PREVENTIVE TREATMENT GUIDELINES FOR TUBERCULOSIS

PURPOSE. The Federal BOP Preventive Treatment Guidelines for Tuberculosis provide recommended guidelines for tuberculosis chemoprophylaxis to prevent TB among inmates in federal correctional facilities and at the time of release to the community.

REFERENCES.

Prevention and Control of Tuberculosis in Correctional Facilities, Recommendations of the Advisory Council for the Elimination of Tuberculosis, *MMWR*, Vol. 45/No. RR-8, June 7, 1996. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta, Georgia.

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DEFINITIONS.

Anergy is the inability of a person to react to skin-test antigens (even if the person is infected with the organisms tested) because of immunosuppression.

Booster phenomenon is a phenomenon in which some persons (especially older adults) who are skin tested many years after infection with *M. tuberculosis* have a negative reaction to an initial skin test, followed by a positive reaction to a subsequent skin test. The second positive reaction is caused by a boosted immune response, indicating latent TB infection.

Clinician is a physician or mid-level provider.

Contact is a person who has shared the same air with a person

who has infectious TB for a sufficient amount of time to allow possible transmission of *M. tuberculosis.*

Directly observed preventive therapy (DOPT) is the unit dose administration of TB preventive medication to an inmate by a clinician, nurse, pharmacist, or specially trained pharmacy staff member.

Exposure is the condition of being subjected to an infectious agent that could have a harmful effect. A person exposed to *M. tuberculosis* does not necessarily become infected.

Intradermal is within the layers of skin.

Mantoux method is the most reliable method of tuberculin skin testing, involving the intradermal injection of PPD-tuberculin into the forearm with a needle and syringe.

Mycobacterium tuberculosis is the mycobacterial species that is the primary cause of active TB disease in the United States.

Positive PPD reaction is the induration measured in millimeters that develops after the intradermal injection of PPD-tuberculin indicative of previous infection with *M. tuberculosis*. The extent of induration that determines a positive test depends on the medical history and risk factors of the person being tested in accordance with the following:

5 millimeters - positive for:

- # Close contacts of an active case of TB.
- # Persons with HIV infection or other immunocompromised conditions, or persons with HIV risk factors and unknown HIV serostatus.
- # Persons with evidence of old tuberculosis infection by chest radiograph.

10 millimeters - positive for correctional staff and inmates.

Preventive therapy or chemoprophylaxis is the treatment of latent inactive TB infection with an antibiotic to prevent the development of active TB disease.

Purified protein derivative (PPD) tuberculin skin test is a method used to evaluate the likelihood that a person is infected with *M. tuberculosis*.

Recent convertor is an individual who has a measured tuberculin skin test that has increased within the past 24 months from a

baseline of 0-9 millimeters of induration by (1) 10 millimeters or more if < 35 years of age; by (2) 15 millimeters or more if 35 years of age or older; by (3) 5 millimeters or more if immunocompromised, regardless of age.

Tuberculosis infection is the condition in which living *M. tuberculosis* organisms enter the body and can elicit a response from the host's immune defenses. TB infection may or may not result in TB disease.

Tuberculosis disease is the condition in which *M. tuberculosis* infection progresses to clinically active, symptomatic disease.

Two-step testing is a procedure used for the baseline testing of persons who will periodically receive tuberculin skin tests to reduce the likelihood of mistaking a boosted reaction for a new infection. If the initial tuberculin skin test result is classified as negative, a second test is repeated 1-3 weeks later. If the reaction to the second test is positive, it represents a boosted reaction indicating old latent TB infection. If the second test result is also negative, the person is classified as not infected.

PROCEDURES.

a. Screening for TB Infection

Inmates should be screened for TB infection with tuberculin skin testing in accordance with BOP policy; upon incarceration, annually, when TB disease is clinically suspected, and if indicated as part of a TB contact investigation using the following guidelines:

1. Inmates screened for TB infection by tuberculin skin testing should always be interviewed for symptoms of TB disease: chronic cough, hemoptysis, fever, night sweats, and unexplained weight loss. The tuberculin skin test is not a highly sensitive test. On average, 10% to 25% of persons with TB disease will have a negative tuberculin skin test. ANY INMATE WITH SYMPTOMS OF ACTIVE TB SHOULD BE REFERRED TO A PHYSICIAN FOR FURTHER DIAGNOSTIC EVALUATION REGARDLESS OF TUBERCULIN SKIN TEST RESULTS.

2. The test is administered by the Mantoux method through the intradermal injection of 0.1 ml of purified protein derivative (PPD) tuberculin containing 5 tuberculin units (TU) into the volar surface of the left forearm, using a disposable tuberculin syringe. Only BOP Formulary tuberculin solution should be used.

3. The tuberculin skin test should be read by a trained health care worker 48 to 72 hours after injection. A positive reaction may be measurable up to one week after testing and is

considered valid. A negative reaction read after 72 hours is invalid.

4. The tuberculin reaction is quantified by measuring the largest diameter of the indurated area (palpable swelling) on the forearm in millimeters. Erythema (redness) without induration is not significant. THE TUBERCULIN SKIN TEST RESULTS SHOULD ALWAYS BE DOCUMENTED IN MILLIMETERS; NEVER AS POSITIVE OR NEGATIVE.

5. Multi-puncture tests (Tine) are poorly standardized and should not be administered.

6. A self-reported, "previously positive", skin test (without a millimeter reading) is not a contraindication to repeat testing unless a severe reaction has been documented or described by the inmate (e.g. entire arm swelling, blistering). Inmates with a positive documented tuberculin skin test measured in millimeters should not be repeatedly tested.

7. Pregnancy is not a contraindication to tuberculin skin testing.

8. Bacille Calmette-Guerin (BCG) vaccination is not a contraindication to tuberculin skin testing. There is no reliable method for distinguishing tuberculin reactions caused by BCG from those caused by infection with *M. tuberculosis*. A history of BCG vaccination should not be considered when interpreting skin tests, since BCG vaccination is not always effective in preventing new infections with *M. tuberculosis*.

9. Anergy testing is not medically indicated as a component of tuberculin skin testing for inmates. Anergy panel antigens are poorly standardized and the antigenic responses are not necessarily predictive of an adequate cellular immune response to PPD tuberculin.

10. Two-step testing should be considered for sentenced inmates at high risk of boosting who have not received a tuberculin skin test in the past 12 months including the following:

(a) Inmates over 50 years of age

(b) Foreign born inmates

(c) Inmates with a history of BCG vaccination

11. Screening tuberculin skin test readings are valid for one year by BOP policy. PPD documentation during the past year from local jails is acceptable for TB screening purposes, however, repeat tuberculin skin testing is recommended for inmates who have been transferred from local detention centers,

particularly in regions of the country with high rates of TB. For BOP inmates who are transferred frequently to and from local jails, testing should be repeated as recommended by the evaluating clinician, but no more than quarterly.

12. Correctional staff should be screened for TB infection with tuberculin skin testing in accordance with BOP policy upon employment, annually thereafter, and when clinically indicated using the same technique for administration and interpretation of skin-tests that is used for the inmate population.

b. Baseline Evaluation for Preventive Therapy

Inmates with tuberculin skin tests of 5 millimeters of induration or greater should be referred for evaluation by a physician for possible TB preventive therapy, which SHOULD NEVER BE INITIATED UNTIL ACTIVE TUBERCULOSIS DISEASE HAS BEEN ELIMINATED AS A DIAGNOSIS WITH A NEGATIVE CHEST RADIOGRAPH AND A DOCUMENTED NEGATIVE ASSESSMENT FOR SIGNS AND SYMPTOMS OF TB. SYMPTOMATIC INMATES SHOULD BE EVALUATED WITH SPUTUM SMEARS AND CULTURES X 3 FOR TB REGARDLESS OF CHEST RADIOGRAPH FINDINGS PRIOR TO CONSIDERING PREVENTIVE VERSUS ACTIVE TREATMENT OF TB.

Baseline evaluation for preventive tuberculosis treatment should include, but not necessarily be limited to the following:

1. Medical history for symptoms of active TB disease, hepatitis, liver disease, pregnancy, and medication review.

2. Targeted physical examination by a physician.

3. Posterior-anterior chest radiograph (pregnant women should not receive a chest radiograph unless they have symptoms of pulmonary TB or have medical indications for isoniazid therapy during pregnancy).

4. Hepatocellular enzymes and other laboratory tests as clinically indicated.

5. HIV counseling and testing.

6. Inmates with chest radiograph abnormalities or symptoms of TB disease should be evaluated for active disease with sputum smears and cultures, prior to initiating preventive therapy.

c. Indications for TB Chemoprophylaxis

Indications for initiating TB preventive therapy are based on the inmate’s tuberculin skin test reaction in millimeters, potential for developing TB disease, and risk factors for drug side effects, such as age, gender, race, and baseline liver

function. TB chemoprophylaxis should be considered when the following indications have been identified, no medical contraindications to treatment exist, and previous adequate treatment can not be documented:

1. Tuberculin skin test is 10 mm or greater for any inmate less than 35 years of age.

2. Recent convertor status: an individual who has a measured tuberculin skin test that has increased within the past 24 months from a baseline of 0-9 millimeters of induration by (1) 10 millimeters or more if < 35 years of age; or by (2) 15 millimeters or more if 35 years of age or older; or by (3) 5 millimeters or more with HIV infection or other immunocompromised condition (Since the criteria for determining recent convertor status are somewhat arbitrary, and relevant medical conditions may not be apparent at the time of skin-testing, all inmates who have an increase in their skin-test reading by 5 millimeters or more during routine screening should be referred to a clinician for further evaluation to determine if TB chemoprophylaxis is medically indicated).

3. Tuberculin skin test is 5 millimeters or greater regardless of age, with the following concurrent conditions that increase the risk of tuberculosis disease:

(a) Close contact to an active TB case.

(b) HIV infection, risk factors for HIV infection with unknown HIV serostatus, or other immunocompromised condition.

(c) Systemic corticosteroids or other immunosuppressive therapy (equivalent to 15 mg. of prednisone or greater for 3 months or more of treatment).

(d) Fibrotic changes on chest radiograph suggestive of inactive pulmonary tuberculosis.

4. Tuberculin skin test is 10 millimeters or greater regardless of age with the following concurrent conditions that increase the risk of TB disease:

(a) Injection drug use history.

(b) Hematologic or reticuloendothelial neoplasms.

(c) Renal failure (dialysis-dependent).

(d) Diabetes mellitus (insulin dependent).

(e) Gastrectomy and other specific conditions resulting

in nutritional deficiencies.

(f) Head and neck malignancies.

(g) Silicosis.

5. Inmates with HIV infection or other immunocompromised conditions who are close contacts of an active TB case should be prescribed TB chemoprophylaxis even if their tuberculin skin test measures 0 millimeters with or without evidence of anergy.

6. Inmates should not be considered for TB preventive therapy if their anticipated incarceration is less than 6 months unless the following high priority indications have been identified:

(a) HIV co-infection or other immunocompromised condition

(b) Close contact of an active TB case

(c) Recent convertor status

7. TB chemoprophylaxis should not be initiated when contraindications to isoniazid or other preventive medication exist, including but not limited to the following:

(a) History of severe reaction to isoniazid or other preventive agent

(b) Radiologic or clinical evidence of active TB disease

(c) Symptoms of active hepatitis

(d) Liver enzymes 3-5 times normal (Preventive therapy may be indicated despite liver enzyme elevations for certain high risk individuals. Consult with a TB expert for high risk candidates with liver disease).

d. TB Preventive Therapy

1. Isoniazid is the standard TB preventive agent prescribed as 15 mg/kg; (max:900 mg) by mouth, twice weekly and administered by unit dose under direct observation (DOPT) at least two days apart. Twice weekly isoniazid should be prescribed for 52 doses (approximately 6 months) for inmates with known HIV seronegative status; and for 78 doses (approximately 9 months) for inmates with HIV seropositive status or unknown HIV serostatus. At the discretion of the treating physician, isoniazid may also be prescribed daily as 5 mg/kg; (max:300 mg) by mouth, and administered by DOPT for 182 doses (approximately 6 months) for inmates with known HIV seronegative status; and daily for 273

doses (approximately 9 months) for inmates with HIV seropositive status or unknown HIV serostatus. A 12 month course of isoniazid should be prescribed for inmates with fibrotic lung disease or silicosis.

2. Completion of isoniazid chemoprophylaxis should be determined by counting doses of isoniazid taken, not solely by duration of treatment, since missed doses may occur.

3. For inmates who miss doses of isoniazid or have histories of incomplete isoniazid compliance the following general guidelines can be applied:

(a) For a one-time or cumulative break less than or equal to two months of prescribed isoniazid or less, resume isoniazid as initially ordered and extend treatment for the number of missed doses.

(b) For a one-time break exceeding a two month regimen of prescribed isoniazid, reinitiate isoniazid therapy, (i.e. start treatment again).

(c) For cumulative multiple breaks exceeding the equivalent of two months of prescribed isoniazid, extend isoniazid therapy by three months (26 doses, if prescribed biweekly).

4. Pyridoxine should be prescribed concurrently as 50 mg daily by mouth while taking isoniazid, since pyridoxine will prevent neuropathy and other isoniazid-related side effects in certain inmates.

5. An alternative TB preventive treatment regimen is rifampin 10 mg/kg (max:600 mg) given orally, daily and pyrazinamide 15-30 mg/kg (max:2 gm) given orally, daily both for 2 months. All doses must be administered by direct observation. The same guidelines for monitoring hepatotoxicity from isoniazid should be used for inmates taking rifampin and pyrazinamide. A complete blood count and platelet count should be obtained prior to initiating rifampin, and repeated as clinically indicated. Pyrazinamide may cause elevations in serum uric acid levels. Asymptomatic hyperuricemia usually does not require treatment. Inmates with active gout should not be prescribed pyrazinamide, except in unusual circumstances when no other treatment options are available.

Dual preventive therapy with rifampin and pyrazinamide is as effective as isoniazid in preventing active TB in studies that have compared the two regimens, although the long term prophylactic efficacy of rifampin and pyrazinamide is still being evaluated. Rifampin and pyrazinamide may be considered in the following high-risk clinical situations:

(a) Inmates with HIV infection who are not taking protease inhibitors or nonnucleoside reverse transcriptase inhibitors and do not have other contraindications to rifampin or pyrazinamide, for whom a two month chemoprophylaxis regimen is preferred for clinical or logistical reasons.

(b) Inmates who can not tolerate isoniazid or have had an adverse reaction.

(c) Inmates who can not complete a 6 month treatment regimen of isoniazid for logistical reasons, but for whom TB prophylaxis is a high priority (e.g. HIV infection, close contact).

Rifampin is contraindicated for inmates with HIV co-infection who are prescribed protease inhibitors or nonnucleoside reverse transcriptase inhibitors. Rifabutin (150 mg given orally, daily) may be substituted for rifampin for TB chemoprophylaxis for inmates prescribed indinavir and nelfinavir, but is contraindicated with ritonavir, hard-gel saquinavir, and delavirdine. Data on the interactions of rifabutin with other protease inhibitors and nonnucleoside reverse transcriptase inhibitors are limited. Rifabutin toxicity may result when prescribed with antiretroviral agents; monitor closely for arthralgias, symptoms of uveitis, leukopenia, and liver dysfunction. Dosage adjustments in antiretroviral medications may be indicated when using rifabutin; consultation with an expert in treating HIV infection/TB is recommended.

6. Specialized TB preventive treatment regimens may be indicated for contacts of resistant TB cases and should be prescribed in consultation with a TB expert.

7. TB chemoprophylaxis is not routinely recommended during pregnancy although no harmful effects on the fetus have been observed. Isoniazid should be prescribed 1-2 months following delivery in most cases. Pregnant women with a positive tuberculin skin test who are a close contact of an active TB case, are recent convertors, or have concurrent HIV infection or other immunosuppressive conditions should be considered for isoniazid chemoprophylaxis while pregnant. Screening chest radiographs should be obtained with appropriate shielding of the fetus.

8. Inmates failing to complete TB chemoprophylaxis prophylaxis on two or more occasions, should be evaluated on a case by case basis to determine if additional retreatment efforts are clinically prudent based on the inmate's risk factors for TB disease, previous cumulative doses of administered preventive therapy, and anticipated adherence to therapy.

e. Monitoring TB Preventive Therapy

1. All inmates receiving TB preventive therapy should be evaluated by health care staff in accordance with the following guidelines:

(a) Baseline evaluation by a physician (0 months).

(b) Monthly follow-up evaluations (0 through 6-12 months) by a clinician for complicated cases included all symptomatic inmates and high risk inmates (those requiring monthly liver enzyme studies).

(c) Periodic clinician evaluations as medically indicated and determined by the Clinical Director.

(d) Monthly inmate interviews for medication side effects or other symptoms by pharmacy or nursing staff.

2. Inmates receiving TB chemoprophylaxis should have hepatocellular enzymes monitored in accordance with the following:

(a) Liver transaminases (ALT and/or AST) should be obtained prior to initiating TB preventive therapy for all inmates. If elevated, complete liver function studies (LFTS) and screening for HBV and HCV infections (HBsAg/anti-HCV) should be obtained.

(b) Chemoprophylaxis should usually not be initiated if liver transaminases are 3-5 times greater than normal. Inmates with liver transaminases 3-5 times normal with a high risk for TB (e.g. HIV infection, close contacts) should be considered for preventive therapy in consultation with a TB expert.

(c) Monthly monitoring of liver enzymes should be considered for persons at high risk for drug-induced hepatitis, including but not necessarily limited to the following persons:

(1) Persons with baseline liver enzymes greater than normal.

(2) Persons 35 years of age or older.

(3) Persons with chronic liver disease from alcohol, viral hepatitis or other etiologies.

(4) Persons concurrently prescribed other

potentially hepatotoxic drugs.

(5) Persons with a history of previous adverse reactions to the chemopreventive agent.

(6) Pregnant women.

3. All inmates receiving TB preventive therapy should be monitored for symptoms of hepatitis and other drug side effects by a pharmacist, clinician or nurse at least monthly. Inmates reporting potential drug side effects should be referred to a physician for further evaluation. ISONIAZID SHOULD BE DISCONTINUED IF LIVER ENZYMES INCREASE TO 3 to 5 TIMES NORMAL OR GREATER, WITH SYMPTOMS OF HEPATITIS, OR OTHER SERIOUS DRUG SIDE EFFECTS

4. Chest radiographs, other than baseline, are not indicated during therapy for inmates prescribed TB preventive therapy unless symptoms of TB develop during treatment.

5. Inmates who are candidates for TB preventive therapy, but decline treatment, or have treatment discontinued because of drug side effects, nonadherence, or other reasons, should be monitored in accordance with the following:

(a) Semiannual chest radiographs and clinician evaluations for symptoms and signs of pulmonary TB for inmates with HIV infection (or unknown HIV serostatus) or other immunosuppressive conditions.

(b) Semiannual chest radiographs and clinician evaluations for symptoms and signs of pulmonary TB for two year period, for HIV seronegative inmates who are recent convertors or close contacts of active tuberculosis cases.

(c) Inmates should be counseled during clinician evaluations to reconsider initiation of TB preventive therapy if appropriate.

f. Documentation

1. TB preventive treatment should be documented by the evaluating physician and other designated staff using the Federal Bureau of Prisons Tuberculosis Chemoprophylaxis Record, (Appendix 1). The form should be maintained in the inmate’s medical record and documentation updated:

(a) At the baseline evaluation and initiation of treatment.

(b) Whenever treatment is interrupted or discontinued.

(c) At the completion of chemoprophylaxis.

2. Medication administration of tuberculosis chemoprophylaxis should be documented using the Federal Bureau of Prisons Tuberculosis Preventive Treatment Program Medication Administration Record (BP-634(60)).

3. Side effects to TB preventive treatment should be monitored monthly by a trained health care provider using the Federal Bureau of Prisons Monthly INH Side Effect Interview and Monitoring Form, (Appendix 2). The form requires the inmate’s signature upon the initiation of treatment and should be reviewed monthly with inmates at each pyridoxine renewal. (Health care staff should read the form to illiterate inmates). The form should be maintained by pharmacy staff, made available to clinicians for review, and a copy placed in the inmate's medical record at the completion or discontinuation of TB preventive treatment.

4. Inmates who refuse TB chemoprophylaxis should sign a refusal form in their medical record, documenting their declination of treatment.

ATTACHMENTS.

Appendix 1. Federal Bureau of Prisons Tuberculosis Chemoprophylaxis Record

Appendix 2. Federal Bureau of Prisons Monthly Isoniazid Side Effect Interview and Monitoring Form

Appendix 1

Federal Bureau of Prisons Tuberculosis Chemoprophylaxis Record

Demographics

Name: (Last) _____ (First) _____ Reg #: _____DOB: __/__/__
Age: ___ Sex: __ Race: W B Asian Hispanic Nat. Amer.

Medical History

PPD: Current test: Date __/__/__ ___mm; Previous test: Date __/__/__ ___ mm Unknown
HIV status: Positive Negative Not tested Date tested: __/__/__ BCG: Y N Chest x-ray: Negative Abn Fibrotic Lesion (old TB) Other _____Previous INH: Y N DOPT: Y N Adverse rx: Y N _____

Indication(s) for Preventive Rx

Close contact Recent convertor Age < 35 Clinical condition _____

Screening History and Exam

Jaundice/hepatitis hx Y N Dark urine Y N Wt loss Y N Cough/TB symptoms Y N
Liver disease Y N Pregnancy Y N Other symptoms/conditions: _____
_____Examination: T ____ P _____
R ____ BP _____ Weight: ___ lbs _____ kgs
_____

Treatment History

INITIATION
Start date: ___/___/___ Drug tx: _____ mgms. Freq _____ Duration _____ doses
Prescribing clinician: Name _____ Facility: _____

DISCONTINUATION
Preventive treatment interrupted or discontinued prior to prescribed duration - list indication(s):
Active case Deceased Released Inmate decision Adverse rx Medical advice
Noncompliance Other : _____

Doses taken: _____ Discontinuation date: ___/___/____
Evaluating clinician: Name _____ Facility: _____

COMPLETION
Doses taken : _____

Preventive treatment completion date: __/__/___ Facility: _____
Comments: _____
_____
_____
_____
_____
_____

Appendix 2

MONTHLY INH SIDE EFFECT INTERVIEW AND MONITORING FORM

INH is an antibiotic that is the first line treatment for latent tuberculosis infection. As with all medications, there are side effects that can occur from its use. INH may affect your body's stores of vitamin B6. For this reason it is absolutely mandatory that you take the vitamin B6 prescribed daily. Failure to do this could contribute to many of the side effects listed below.

I have read and understand this form and agree to accurately record any potential side effects I may experience monthly when I am interviewed as below:

X_____ _____ _____
Signature **Printed Name/Register Number** **Date**

Record either a "Y" for yes or a "N" for no at each symptom or sign monthly:

Month:	1	2	3	4	5	6	7	8	9	10	11	12
numb hands/feet												
headache												
seizure												
vision decrease												
memory loss												
loss of appetite												
nausea/vomiting												
yellow skin or eyes												
fatigue/wt. loss												
abdominal pain												
brown urine												
Initial monthly:												
Inmate												
MD/PA/RN/RPH												

Termination of Medication date:_____

Physician/PA/NP Comments: ("Y" response requires brief note here and immediate referral to clinician for evaluation and documentation of treatment plan in medical record)

_____

_____

ENTRAVISTA Y FORMA PARA REGULAR MENSUALMENTE LOS EFECTOS DE INH

INH es un antibiotico que trata la forma latente de la Tuberculosis. Como con todos los medicamentos, pueden ocurrir efectos seundarios con su uso. INH puede afectar la reserva de la vitamina B6 en su cuerpo. Por este motivo es absolutamente mandatorio que tome la vitamina B6 recetada diariamente. No tomar la vitamina B6 puede contribuir a los varios efectos secundarios identificados abajo.

Yo he leido y entendido esta forma y estoy de acuerdo en documentar mensualmente si tengo algunos de estos sintomas cuando me entrevisten.

_____ _____ _____

Firma **Nombre Escrito y Numero de Registro** **Fecha**

Indique con una "Y" para SI o con una "N" para No al lado cada sintoma.

MES:	1	2	3	4	5	6	7	8	9	10	11	12
adormecimiento de pies/manos												
dolor de cabeza												
ataque epileptico / convulsiones												
perdida de vision												
perdida de memoria												
falta de apetito												
nauseas/vomitos												
piel u ojos amarillos												
dolor abdominal												
orina color café												
Firme con sus iniciales cada mes:												
RECLUSO												
MD/PA/RN/RPH												

Termination of medication date: _____

Physician/PA/NP comments: ("Y" response requires brief note here and immediate referral to clinician for evaluation and documentation of treatment plan in medical record)

_____

_____

BOP Treatment Guidelines for Sexually Transmitted Diseases*

Infection	Treatment (Directly observed)	Comments
Gonorrhea - *N. gonorrhoeae* urethritis, cervicitis, pharyngitis, or rectal infection	Ciprofloxacin 500 mg orally x 1; OR Ceftriaxone 125 mg IM x 1 PLUS empiric treatment for chlamydial infection: Azithromycin 1 gram orally x 1; OR Doxycycline 100 mg BID orally x 7 days	Culture symptomatic inmates at the time of diagnosis (dx). Follow-up cultures to prove cure are not indicated unless symptoms persist. Disseminated GC requires systemic (IV) treatment (tx) until clinical improvement. Tx regimens are the same for inmates with HIV co-infection. Pregnant women should be treated with a cephalosporin (GC) and erythromycin (chlamydia). Evaluation and treatment of all sex partners is indicated for contacts within 60 days of symptoms or dx.
Syphilis - *T. pallidum*	Primary, secondary, or early latent (< 1 yr) syphilis: Benzathine penicillin - 2.4 million units IM X 1 PCN allergy - tetracycline 500 mg QID orally x 2 weeks Syphilis of unknown duration, late latent syphilis, and tertiary syphilis: Benzathine penicillin - 7.2 million units total (2.4 million units IM weekly X 3) PCN allergy - tetracycline 500 mg QID orally x 4 weeks Neurosyphilis/syphilitic eye disease (e.g. uveitis): Aqueous crystalline penicillin G -18-24 million units daily (3-4 million units IV every 4 hrs for 10-14 days**)**	Penicillin (PCN) allergic inmates with pregnancy or neurosyphilis should be desensitized and treated with PCN only. Inmates with late latent syphilis or syphilis of unknown duration should have a CSF evaluation with the following: tx failure, HIV infection, signs of tertiary syphilis, unexplained neuro/eye disease. All inmates with syphilis should be tested for HIV. HIV co-infected inmates can be treated with standard syphilis regimens, but require closer monitoring of serologies and CSF (as indicated). Inmates with pregnancy, HIV co-infection, and tertiary disease should be managed in consultation with an expert since additional tx recommendations may be indicated. Sex partners of contagious cases should be evaluated for infection. All contacts exposed < 90 days preceding the dx of primary, secondary, or early latent syphilis should be empirically treated (inmates with syphilis of unknown duration with RPR titers 1:32 should be considered as having early syphilis for empiric tx of contacts). Contacts exposed > 90 days preceding the dx of contagious syphilis should be evaluated for infection and treated if medically indicated.

*Adapted from Centers for Disease Control Guidelines, *MMWR*, Vol. 47, January, 23, 1998

BOP Treatment Guidelines for Sexually Transmitted Diseases*

Infection	Treatment	Comments
Chlamydia - C. trachomatis genital infection	Azithromycin 1 gm orally x 1; OR Doxycycline 100 mg orally BID x 7 days; OR Erythromycin base - 500 mg orally QID x 7 days (Directly observed tx)	Confirm infection by culture or other assay whenever possible. Asymptomatic infection is common in men and women. Inmates should not be routinely tested for cure following tx of chlamydial infections with azithromycin or doxycycline. A test of cure should be performed > 3 weeks after tx, if the inmate has persistent symptoms or is treated with erythromycin. Pregnant women should be treated with erythromycin base or amoxicillin. The most recent sex partner and any sex partners in contact with the index case during the 60 days preceding the onset of symptoms should be evaluated for chlamydia.
Herpes simplex virus (HSV) - genital infection First episode Recurrent episodes Suppressive tx	 Acyclovir 400 mg TID orally for 7-10 days Acyclovir 400 mg TID orally for 5 days Acyclovir 400 mg BID orally x 1 year	Sexual transmission of HSV can occur in asymptomatic individuals. Recurrent episodes of genital herpes can be treated with some symptomatic relief if tx is initiated within 1 day after onset of lesions. Topical acyclovir is ineffective. Suppressive tx can be considered in persons with 6 or more episodes of genital infections/year. Suppressive tx does not eliminate asymptomatic viral shedding. Continuation of suppressive tx should be reconsidered after 1 year. Immunocompromised persons require IV acyclovir for disseminated disease and may require higher doses of oral acyclovir for localized infections.
Vaginitis Trichomoniasis Candidiasis Bacterial Vaginosis	 Metronidazole 2 gm orally x 1 Clotrimazole 500 mg vaginal tab x 1 OR; other topical agent Metronidazole - 500 mg orally BID x 7 days	Immunocompromised patients usually respond to recommended regimens. Recurrent vulvovaginal candidiasis, RVVC, (4 or more episodes/yr) is associated with HIV and diabetes. Maintenance therapy should be considered for RVVC in consultation with an expert. Empiric tx of sex partners is indicated for trichomoniasis. BV is associated with adverse outcomes in pregnancy: screen and tx in consultation with obstetrician or other expert.
Venereal Warts Human papilloma virus (HPV)	Topical - podophyllin or trichloroacet. acid Cryotherapy Surgical excision	Primary goal should be the removal of symptomatic warts. No evidence indicates that tx eradicates HPV, and removal of warts may or may not decrease infectivity. Visible warts may resolve spontaneously. Choice of tx depends on wart location/severity. Always tx warts if HIV co-infection is present, since warts may spread/multiply requiring surgery.

*Adapted from Centers for Disease Control Guidelines, MMWR, Vol. 47, RR-1, January 23, 1998

Diagnosis and Monitoring Strategies for Syphilis*

Syphilis Stage	Monitoring	Comments
Primary/ Secondary	HIV (-) RPR q 6 months HIV (+) RPR q 3 months	If RPR rises fourfold or inmate remains symptomatic then evaluate CSF and retreat with benzathine PCN 2.4 million units IM weekly x 3 or for neurosyphilis if indicated. Failure of RPR to decline fourfold in 6 months after initial tx suggests possible tx failure: repeat HIV serology if HIV (-), consider CSF exam, and consider retreatment as above.
Latent	HIV (-) RPR - 6, 12, 24 m. HIV(+) RPR - 6, 12, 18, 24 m CSF evaluation if HIV+ and late latent syphilis or syphilis of unknown duration	Inmates should be retreated and evaluated for neurosyphilis IF: titers increase fourfold, a titer 1:32 fails to decline fourfold within 12-24 months, or with signs/symptoms of syphilis. Use low threshold for evaluating or re-evaluating CSF in HIV seropositive persons.
Tertiary (cardiovascular, gummatous)	Clinical evaluations regularly with RPR titers Screening CSF evaluation	Monitor clinical response to tx in consultation with an expert to assess effectiveness of treatment.
Neurosyphilis	RPR titers periodically CSF cell count, glucose, protein, and VDRL every 6 months	Monitor clinical response to tx and CSF every 6 months until pleocytosis has normalized. Changes in CSF-VDRL and CSF protein are less reliable barometers of tx efficacy. If CSF cell counts remain elevated at 2 yrs: consider retreatment.

A. A presumptive diagnosis of syphilis can be made by two types of serology: (1) quantitative nontreponemal serologic assays (e.g. Venereal Disease Research Laboratory (VDRL) or RPR), and (2) confirmatory treponemal assays (e.g. fluorescent treponemal antibody absorbed (FTA-ABS) and microhemagglutination assay for antibody to *T. pallidum* (MHA-TP). The confirmatory assay is essential, because non-treponemal assays are frequently false-positive due to concurrent medical conditions, including injection drug use history.

B. Nontreponemal assays tend to correlate with disease activity. A clinically significant difference between two tests requires at least a fourfold change in titer. The assay should become nonreactive with treatment, but some persons will remain serofast with a low titer for life despite adequate tx. Serologic titers may decline more slowly for persons with recurrent syphilis.

C. Treponemal assays (e.g. FTA-ABS) usually remain positive for life, however 15%-25% of persons treated during primary syphilis may revert to a nonreactive status after 2-3 years.

D. Serologic tests for syphilis in persons with HIV infection are generally more variable, but should still be considered accurate and reliable for diagnosis and evaluating treatment response.

E. Neurosyphilis is diagnosed by clinical or laboratory findings. A positive CSF-VDRL (in the absence of significant blood contamination) is considered diagnostic of neurosyphilis. A negative CSF-FTA-ABS excludes nearly all cases of neurosyphilis.

*Adapted from CDC 1998 Treatment Guidelines for STDs, MMWR, Vol. 47/No. RR-1, January 27, 1998.

Endocarditis Prophylaxis - Risk Categories*

HIGH RISK - Prophylaxis Recommended for Certain Procedures

- Prosthetic cardiac valves
- Previous bacterial endocarditis
- Cyanotic congenital heart disease (complex); e.g. tetrology of Fallot, single ventricle
- Surgically constructed systemic pulmonary shunts

MODERATE RISK - Prophylaxis Recommended for Certain Procedures

- Valvular dysfunction (acquired), e.g. rheumatic heart disease
- Hypertrophic cardiomyopathy
- Mitral valve prolapse with valvular regurgitation and/or thickened leaflets**
- Congenital cardiac malformations (uncomplicated and uncorrected):
  Patent ductus arteriosus
  Coarctation of the aorta
  Ventricular septal defect
  Atrial septal defect (primum)
  Bicuspid aortic valve

NEGLIGIBLE RISK - Prophylaxis NOT Recommended

- Atrial septal defect (isolated secundum)
- Repaired ASD, VSD, or PDA (without residua beyond 6 months)
- Mitral valve prolapse without valvular regurgitation or thickened leaflets
- Rheumatic fever history without valvular dysfunction
- Kawasaki disease history without valvular dysfunction
- Coronary artery bypass graft surgical history
- Cardiac pacemakers and implanted defibrillators
- Physiologic/functional heart murmurs (structurally normal heart)

* Adapted from Prevention of Bacterial Endocarditis: Recommendations by the American Heart Association, JAMA, 1997;277:1794.

** Persons with prolapsing and leaking mitral valves (diagnosed by audible clicks and murmurs of mitral regurgitation or echocardiography) or thickened mitral valves (myxomatous degeneration) are candidates for prophylaxis.

Endocarditis Prophylaxis - Dental Procedures*

Endocarditis Prophylaxis <u>Recommended</u> - High/Moderate Risk Conditions**

- Dental extractions
- Dental implant placement and reimplantation of avulsed teeth
- Endodontic (root canal) instrumentation or surgery only beyond the apex
- Subgingival placement of antibiotic fibers or strips
- Initial placement of orthodontic bands, but not brackets
- Intraligamentary local anesthetic injections
- Prophylactic cleaning of teeth or implants where bleeding is anticipated
- Periodontal procedures: surgery, scaling, root planing, and probing

Endocarditis Prophylaxis <u>NOT Recommended</u>

- Restorative dentistry (operative and prosthodontic) ***
- Local anesthetic injections (nonintraligamentary)
- Intracanal endodontic treatment; post placement and buildup
- Placement of rubber dams
- Postoperative suture removal
- Placement of removable prosthodontic or orthodontic appliances
- Taking oral impressions
- Fluoride treatments
- Taking oral radiographs
- Orthodontic appliance adjustments

* Adapted from Prevention of Bacterial Endocarditis: Recommendations by the American Heart Association, JAMA, 1997;277:1794.

** Gentle oral rinsing with 15 milliliters of chlorhexidine for 30 seconds prior to the procedure may reduce bacteremia in at-risk patients.

*** Clinical judgment may warrant endocarditis prophylaxis in certain cases where significant bleeding is anticipated.

Endocarditis Prophylaxis

Respiratory, Gastrointestinal and Genitourinary Tract Procedures*

Prophylaxis Recommended for High/Moderate Risk Conditions

- Tonsillectomy and/or adenoidectomy
- Surgeries involving the respiratory mucosa
- Bronchoscopy with a rigid bronchoscope
- Prostate surgery
- Cystoscopy and urethral dilation

Prophylaxis - Recommended for High Risk Conditions
Optional for Moderate Risk Conditions

- Sclerotherapy for esophageal varices
- Esophageal stricture dilation
- Endoscopic retrograde cholangiography with biliary obstruction
- Biliary tract surgery and intestinal surgery involving the mucosa

Prophylaxis - Optional for High Risk Conditions
Not Recommended for Moderate Risk Conditions

- Bronchoscopy with a flexible bronchoscopy, with or without biopsy
- Transesophageal echocardiography
- Endoscopy with or without gastrointestinal biopsy
- Vaginal hysterectomy and vaginal delivery

Prophylaxis Not Recommended

- Endotracheal intubation
- Tympanostomy tube insertion
- Cesarean section
- Cardiac catheterization, including angioplasty
- Cardiac pacemaker, implantable defibrillator, and coronary stent placements
- Circumcision
- Incision or biopsy of surgically scrubbed skin
- GU procedures involving uninfected tissue: urethral catheterization; uterine dilatation and curettage; abortion, sterilization, and insertion or removal of intrauterine devices

***** Adapted from Prevention of Bacterial Endocarditis: Recommendations by the American Heart Association, JAMA, 1997; 277:1794. Documented infections, e.g. UTI, should be treated prior to elective procedures regardless of risk category.

Antibiotic Regimens for Endocarditis Prophylaxis*

Dental, Oral, Respiratory Tract, and Esophageal Procedures

CATEGORY	ANTIBIOTIC	REGIMEN
Standard prophylaxis	Amoxicillin	2 grams orally 1 hr before procedure
Unable to take oral drug	Ampicillin	2 grams IM or IV within 30 minutes of procedure
Penicillin allergy	Clindamycin; OR Azithromycin; OR Cephalexin**	600 mg orally 500 mg orally 2 gms orally given 1 hr before procedure
Penicillin allergy and unable to take oral drug	Clindamycin; OR Cefazolin**	600 mg IV 1 gm IM or IV within 30 min. before procedure

** Cephalosporins should not be used in persons with immediate-type hypersensitivity reactions (e.g. urticaria, angioedema, or anaphylaxis) to penicillin.

Genitourinary and Gastrointestinal (not esophageal) Procedures

CATEGORY	ANTIBIOTIC	REGIMEN
High-risk	Ampicillin PLUS Gentamicin	2 gm IM or IV 1.5 mg/kg IV (max:: 120 mg) Complete within 30 min. of starting procedure followed 6 hrs. later with ampicillin (1gm IM or IV); OR amoxicillin (1 gm orally)
High-risk/penicillin allergic	Vancomycin PLUS Gentamicin	1 gm IV over 1-2 hrs. 1.5 mg/kg IV (max:: 120 mg) complete within 30 min. of starting procedure
Moderate-risk	Amoxicillin; OR Ampicillin	2 gm orally -1 hr before procedure 2 gm IM/IV-within 30 min of procedure
Moderate-risk penicillin allergic	Vancomycin	1 gm IV over 1-2 hrs - complete within 30 min. of starting procedure

*Adapted from Prevention of Bacterial Endocarditis: Recommendations by the American Heart Association, JAMA, 1997;227:1794

Federal Bureau of Prison Treatment Guidelines for Varicella

PURPOSE. The Federal Bureau of Prisons Treatment Guidelines for Varicella provide recommendations for the medical management and containment of varicella zoster viral infections diagnosed in federal inmates.

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DEFINITIONS.

Herpes zoster, commonly called shingles, is a disease caused by the reactivation of latent varicella zoster.

Varicella, commonly called chicken pox, is a respiratory disease, usually of childhood, caused by varicella zoster virus.

Varicella zoster virus (VZV) is a member of the Herpesviridae family and is the cause of chicken pox and shingles.

PROCEDURES.

a. Diagnosis

1. Varicella/chicken pox. Primary infection with VZV results in clinical chicken pox in approximately two weeks with the incubation period ranging from 10-21 days. Chicken pox is an acute viral illness that normally presents with mild constitutional symptoms and the sudden onset of a maculopapular rash that rapidly evolves to a vesicular exanthem. The rash classically spreads centripetally from the trunk in successive crops resulting in lesions in various stages of evolution including, papules, vesicles, pustules and crusted lesions. Atypical, subclinical cases of varicella without a rash are rare,

but do occur. Although most cases of chicken pox are self-limited without serious sequelae, serious, potentially life threatening complications can occur, including encephalitis, pneumonia, and hepatitis. Newly infected adults and immunocompromised persons are at greater risk for serious complications.

The diagnosis of chicken pox can usually be made clinically without laboratory confirmation. A Tzanck prep of the base of the vesicle, revealing characteristic multi-nucleated giant cells is indicative of a *herpes* infection and is suggestive of chicken pox, but not diagnostic. VZV isolation on culture is confirmatory. Primary infection with VZV nearly universally results in lifelong immunity and measurable protective antibodies.

Primary infection with VZV during pregnancy may result in viral transmission to the fetus or newborn. Intrauterine transmission of VZV can result in congenital varicella syndrome, neonatal varicella, or herpes zoster during infancy. Congenital varicella syndrome, is most commonly associated with primary VZV maternal infection during the first trimester of pregnancy and is characterized by low birth-weight, limb deformities, and ocular problems in the newborn. Maternal infection with VZV 5 days before to 2 days after delivery is associated with severe, potentially fatal perinatal chicken pox in the newborn infant.

2. Herpes zoster/shingles. Following primary infection with VZV(chicken pox) the virus becomes dormant in the sensory-nerve ganglia of the nervous system. Reactivation of VZV occurs sporadically, but more commonly with increasing age and with immunosuppression. Reactivation is associated with the clinical presentation of herpes zoster, commonly presenting as a severely painful, unilateral dermatomal rash. The rash is initially papular, then vesicular, and eventually crusts in 10-15 days. Cranial nerve involvement results in nerve specific signs (eyelid and nose lesions, indicate potentially sight-threatening keratitis). Severe sequelae are more common with concurrent immunosuppression and include disseminated dermatologic disease, meningoencephalitis, cerebral angiitis, and visceral involvement. Once the rash of herpes zoster has resolved, post-herpetic neuralgia may persist chronically, particularly in persons over 50 years of age.

b. Treatment

1. Chicken pox/varicella. Acyclovir, 800 mg, 5 times/day, administered orally is approved for the treatment of uncomplicated chicken pox in adults. Initiating treatment within 24 hours of the rash, results in fewer lesions and less constitutional symptoms for some infected persons. Pruritus should be treated with topical and if necessary systemic agents,

to minimize scratching and potentially serious secondary bacterial infections. Intravenous acyclovir should be considered for complicated primary VZV infections, particularly in immunocompromised inmates.

2. Herpes zoster/shingles. Acyclovir, 800 mg, 5 times/day, administered orally for 7-10 days is approved for the treatment of adults with herpes zoster. When initiated at the onset of rash, acyclovir therapy accelerates healing of skin lesions, diminishes the associated neuritis, and reduces the risk of developing post-herpetic neuralgia in some persons. The concurrent administration of steroids is of uncertain benefit. Intravenous acyclovir should be considered for disseminated herpes zoster in the immunocompromised inmate.

c. Transmission

1. Varicella/chicken pox. Persons with chicken pox are contagious 1-2 days before developing a rash until skin lesions are crusted (usually for 4-5 days after the rash began). VZV is spread from person to person from respiratory secretions or from the vesicular skin lesions through direct contact, droplet, or aerosol exposures. Secondary attack rates (transmission rates to previously uninfected persons) are extraordinarily high, ranging from 70%-90%. Persons can be infected without immediate contact with an infectious person, however, for contact investigation purposes, direct contact of one hour or greater is usually considered significant.

2. Herpes zoster/shingles. Herpes zoster is usually less contagious that chicken pox, however, VZV can be transmitted by the direct contact, droplet, or aerosol exposures to the vesicular lesions of a person with shingles. The infectiousness of herpes zoster is greatly increased when disseminated disease is present. Transmission of VZV from persons with herpes zoster results in chicken pox in susceptible contacts.

d. Containment

1. Inmates with suspected or confirmed varicella or herpes zoster should be isolated from the general inmate population in accordance with BOP policy. Inmates should be transferred to a community hospital if medically indicated, or otherwise housed in the institution’s negative pressure isolation room (NPIR) or a single cell with restricted contact with other inmates. The inmate can return to general population housing when ordered by a physician and skin lesions have crusted.

2. Only correctional staff who self-report a history of chicken pox should have any contact with an inmate with contagious chicken pox or herpes zoster. (A self-reported history of chicken pox is approximately 98% accurate. A self-

reported unknown or negative history of chicken pox, correlates with an actual history of chicken pox 70-90% of the time). Correctional staff who are pregnant or have reason to believe they may be pregnant should have no contact with an inmate with contagious chicken pox or herpes zoster, regardless of their reported history of chicken pox.

3. Correctional staff entering the cell of a contagious inmate with chicken pox or herpes zoster should wear masks (NIOSH-certified respirators or surgical masks) and gloves when any direct contact with the inmate is anticipated. Disposable masks and gloves should be disposed of as infectious waste.

e. Management of exposures

1. Inmates and correctional staff, who self-report no prior history of chicken pox, who have been exposed (defined as greater than 1 hour of direct indoor contact) to a contagious case of chicken pox or herpes zoster, should be considered potentially contagious 10-21 days after their exposure.

2. Post-exposure prophylaxis

(a) Post-exposure prophylaxis with varicella zoster immunoglobulin (VZIG), administered intramuscularly in accordance with the manufacturer's guidelines, may be indicated for susceptible persons at high risk of complications from chicken pox, including pregnant women, and immunocompromised persons with human immunodeficiency virus (HIV) infection, certain cancers, and other medical conditions. In pregnant women, VZIG does not prevent congenital varicella syndrome or neonatal varicella, but limits the potentially severe complications of chicken pox in the mother. VZIG must be given within 96 hours of exposure for it to have proven efficacy. The incubation period of chicken pox is prolonged to 28 days or greater for exposed persons treated with VZIG.

(b) Post-exposure prophylaxis with acyclovir for nonpregnant susceptible contacts may have some use in limiting or aborting acute varicella, based on its use to date as a preventive treatment, however, the efficacy of acyclovir has not been proven.

(c) Varicella vaccine should not be used for post-exposure prophylaxis for chicken pox.

3. Correctional staff with direct exposure to a case of chicken pox or herpes zoster should be managed in accordance with the following guidelines:

(a) All correctional staff who are pregnant or have reason to believe they may be pregnant, regardless of their self-reported history of previous chicken pox, should be referred to their physician for further evaluation and consultation.

(b) All correctional staff who self-report no history of previous chicken pox should be referred to their physician for further evaluation and consultation. Susceptible, asymptomatic staff may continue to work in the BOP facility, but should be managed in accordance with the following:

(1) Released from work duty if they have signs or symptoms of chicken pox until no longer contagious as determined by their physician.

(2) Susceptible health care staff should not provide direct care to inmates at high risk of severe complications of varicella, including pregnant and immunocompromised inmates.

4. When a case of contagious chicken pox has been diagnosed in the BOP institution, pregnant staff (regardless of their exposure or susceptibility status) should be assigned duties that minimize their contact with other susceptible staff and inmates.

5. All inmates who are exposed to a contagious case of chicken pox or herpes zoster should be managed according to the following guidelines:

(a) Inmate contacts should be interviewed to determine if they have a history of chicken pox or current signs or symptoms of chicken pox. Contacts with signs or symptoms of chicken pox should be isolated from the inmate population.

(b) Inmates <u>without</u> a self-reported history of chicken pox should be considered susceptible to VZV infection 10-21 days after their exposure. Management of susceptible inmates must be determined on a case by case basis by the HSA and Clinical Director with the approval of the Warden, based on the number of inmates affected and clinical, housing, and security issues. The following guidelines should be considered:

(1) Susceptible inmate contacts who are pregnant, or have impaired immunity from HIV infection and certain cancers should be considered for post-exposure prophylaxis with VZIG. Obtaining serologic titers to determine immunity may be

clinically valuable, but prophylaxis should not be delayed beyond 96 hours from the initial exposure. Acyclovir prophylaxis is unproven, but may be considered in certain cases for nonpregnant, at-risk inmate contacts. Practical measures that minimize the interaction of susceptible inmate contacts with other unexposed inmates, should be considered. Absolute quarantine or isolation of susceptible contacts, however, is rarely indicated.

(2) Susceptible inmate contacts should generally not be transferred to other BOP institutions until the incubation period for chicken pox has lapsed. Determining immunity by serology, may be helpful in certain cases, but is not routinely indicated. If susceptible inmate contacts must be transferred for security reasons, the receiving institution should be notified so that the inmate can be segregated from at-risk inmate populations and staff.

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1. An inmate presents to your clinic with new onset jaundice, fever, elevated transaminases and normal alkaline phosphatase. You suspect acute viral hepatitis. How should you confirm the diagnosis?

   A. Measure Hep A IgG, HBsAg, and anti-HCV
   B. Measure Hep A IgM, anti-HBc IgM, and anti-HCV
   C. Measure Hep A IgM, anti-HBs, and anti-HCV
   D. Measure Hep A IgM, anti-HBe, and anti-HCV
   E. Measure Hep A IgG, HBsAg, and anti-HCV

2. Which of the following statements is false regarding the diagnosis of an inmate with hepatitis A?

   A. The estimated period of contagiousness for the inmate is three weeks prior to the onset of jaundice until 10 days after the onset of jaundice.
   B. The inmate is more contagious if he has diarrhea.
   C. If the inmate is a food worker the potential for an outbreak of hepatitis A must be considered.
   D. Immunoglobulin prophylaxis of contacts can be given up to two weeks after exposure.
   E. Hepatitis A vaccine provides effective post-exposure prophylaxis for inmate contacts.

3. Which of the following statements is false regarding HBV infection?

   A. If an inmate is HBsAg+, he is considered a chronic carrier and is contagious.
   B. An inmate with chronic HBV infection (HBsAg+) can spontaneously develop antibodies to HBsAg and clear chronic HBV infection.
   C. If an inmate is HBe antigen positive, he is less contagious.
   D. Reinfection with HBV in unlikely in an inmate who has developed anti-HBs.
   E. Complications of HBV infection, such as cirrhosis and liver cancer usually do not develop until 20-30 years after infection.

4. Which of the following is not an indication for treatment of hepatitis B with interferon alpha?

   A. ALT is elevated 2X normal for 12 months
   B. Anti-HBe+
   C. HBsAg+
   D. HBV DNA +
   E. Fibrosis on liver biopsy

5. Which of the following is false regarding the diagnosis of HCV infection?

   A. The EIA is a highly sensitive test in diagnosing HCV infection in injection drug users.
   B. Inmates with antibodies to HCV (anti-HCV+) are protected from recurrent infections with HCV.
   C. The RIBA test is helpful in confirming HCV infection for persons at low risk for HCV infection or with normal liver transaminases.
   D. Confirming the presence of HCV RNA by qualitative assay is essential before initiating drug therapy for HCV infection.
   E. With acute HCV infection, anti-HCV can be measured with the onset of symptoms in the majority of persons.

6. Which of the following statements is false regarding evaluation of inmates with HCV infection for drug therapy?

   A. Persons with a normal ALT should not be considered for treatment.
   B. A mental health evaluation is essential prior to interferon therapy, since depression is a serious major side effect.
   C. A liver biopsy should be done at baseline prior to initiating drug therapy.
   D. HBV co-infection does not complicate treatment with interferon.
   E. Persons with liver failure should not be treated.

7. Which of the following is false regarding drug therapy for hepatitis C.

   A. Ribavirin should never be given as monotherapy
   B. Hypothyroidism from interferon is often irreversible.
   C. Hemolytic anemia is associated with ribavirin therapy
   D. Interferon/ribavirin can be safely given to pregnant inmates.
   E. Ribavirin and interferon in combination is indicated for inmates with HCV infection who previously had no response to treatment.

8. Which statement is false regarding prevention of hepatitis B and C infections?

   A. All staff should be screened for antibodies to hepatitis B prior to immunization.
   B. Booster doses of hepatitis B vaccine are not routinely indicated for staff.
   C. There is no proven prophylaxis for HCV exposures.
   D. Known hepatitis B vaccine responders do not require booster doses or HBIG if exposed to HBV infection.

E. Staff with percutaneous exposures to HCV should be monitored by measuring antibodies to HCV and liver transaminases.

9. Which of the following statements is false concerning tuberculin skin testing?

A. Testing should be performed using the Mantoux method of intradermal injection.
B. Tests should be read in millimeters (mm.) of induration, not erythema.
C. A reading of 15 mm., 7 days after administering a PPD is valid.
D. A reading of 0 mm., 4 days after administering a PPD is valid.
E. Pregnant women can safely receive a tuberculin skin test.

10. Which of the following is false concerning the assessment of PPD positivity?

A. A 5 mm. PPD is considered positive for inmates with HIV infection.
B. A 10 mm. PPD is considered positive for all inmates, even those without underlying risks for TB.
C. A 5 mm. PPD is considered positive for inmates and staff who are close contacts of an active case of TB.
D. In nearly all cases, an inmate who reports a history of a positive PPD, but has no documented measurement in millimeters, can be safely retested.
E. Millimeter thresholds for PPD positivity are different in persons with BCG vaccination.

11. Which of the following inmates is not a candidate for TB preventive therapy?

A. 60 year old inmate who boosts his PPD from 0 mm. to 15 mm. after two step testing at intake.
B. 55 year old HIV-infected inmate with a 7 mm. PPD at intake.
C. 30 year old healthy inmate with 10 mm. PPD at intake.
D. 26 year old inmate whose PPD increases from 3 mm. to 14 mm. during annual testing
E. 67 year old inmate whose PPD increases from 2 mm. to 20 mm. during annual testing

12. Which of the following inmates is not a candidate for TB preventive therapy?

A. A 20 year old inmate with a new PPD of 6 mm. whose cell mate has been diagnosed with active TB.
B. A 55 year old inmate on renal dialysis with a PPD of 11

mm. at intake.
C. A 30 year old otherwise healthy inmate who has a 20 mm. PPD on intake.
D. A 23 year old inmate with AIDS with a 7 mm. PPD.
E. A 24 year old healthy inmate with a 4 mm. PPD. on intake.

13. Which of the following statements is false concerning isoniazid hepatotoxicity?

A. All inmates should have baseline liver transaminases measured prior to receiving INH.
B. Hepatotoxicity most frequently occurs within 4-8 weeks of initiating INH.
C. An inmate with transaminase levels 2X normal should not be given INH.
D. Inmates at high risk for hepatotoxicity should have monthly liver transaminase measurements.
E. Hepatitis from INH usually resolves when INH is discontinued at the onset of symptoms.

14. You are asked to evaluate an inmate with AIDS who has roomed with a cell mate with active, smear-positive pulmonary TB for one month. How would you manage the inmate with HIV infection after ruling out active TB by symptom review and chest radiograph?

A. Give INH regardless of PPD test results.
B. Give INH if PPD is 5 millimeters or greater.
C. Give INH if PPD is 5 millimeters or greater or less than 5 millimeters with anergy.
D. Give INH if PPD is 10 millimeters or greater.
E. Give INH if PPD is 2 millimeters or greater.

15. Which of the following statements is false concerning treatment of active TB?

A. TB should never be treated by a single drug.
B. Multi-drug resistant TB may require 24 months of treatment with TB drugs.
C. A single drug should never be added to a failing TB drug regimen.
D. Rifampin should not be prescribed with protease inhibitors; an alternative TB treatment regimen is indicated.
E. Initiation of drug therapy with three drugs is the standard BOP treatment regimen.

16. An inmate with smear-positive pulmonary TB should normally be housed in AFB isolation until which of the following

criteria have been met?

A. The inmate is clinically improved.
B. The inmate has been treated with four drug therapy for at least two weeks.
C. The inmate has 3 consecutive, negative AFB smears from sputum.
D. Drug sensitivities are available if multi-drug resistance is suspected.
E. All of the above.

17. Which of the following statements is false regarding the treatment of active TB?

A. If treatment is effective sputum cultures should convert to negative within four months of treatment.
B. Extended treatment may be required with HIV co-infection, particularly with malabsorption.
C. Pyrazinamide often causes hyperuricemia, but this side effect is usually well tolerated.
D. Pregnant women with active TB require treatment, but pyrazinamide and streptomycin should be avoided.
E. Isoniazid, rifampin, pyrazinamide, and ethambutol doses should all be administered daily or biweekly not in split daily dosages.

18. Which of the following statements is false regarding the staging of HIV infection?

A. A person with asymptomatic infection, but CD4+ T-cells of 120/mm^3 should be staged as A3.
B. A person previously staged as C3 with CD4+ T-cells of 100/mm^3 that increases to 300 when placed on protease inhibitors should be reclassified as C2.
C. An asymptomatic person with CD4+ T-cells of 250/mm^3 with a CD4+ T-cell percentage of 10% should be classified as A3.
D. A person with oral candidiasis and CD4+ T-cells of 340/mm^3 should be classified as B2.
E. A person with PCP pneumonia and CD4+ T-cells of 220/mm^3 should be classified as C2.

19. Which of the following statements is false regarding the measurement of plasma HIV RNA?

A. Plasma HIV RNA should not be measured within one month of immunizations or acute illnesses.
B. The nadir (lowest level) of HIV RNA may not be reached for 2-4 months after changing anti-retroviral therapy.

C. HIV RNA can return to pretreatment levels within several days of stopping anti-retroviral therapy.
D. A tenfold (1 log) change in plasma HIV RNA one month after initiating an anti-retroviral regimen often predicts undetectable viral levels at 4-6 months.
E. If CD4+ T-cell counts are stable and the inmate is asymptomatic plasma HIV RNA testing is not indicated.

20. Which of the following is not indicated during baseline evaluation of an inmate with HIV infection?

A. Chest radiograph
B. Plasma HIV RNA testing
C. Anergy panel
D. Pneumovax, with a booster in 5 years
E. Influenza vaccination before flu season
F. Toxoplasmosis IgG titer

21. Which of the following statements is false regarding nucleoside reverse transcriptase inhibitors (NRTIs)?

A. AZT and d4T are antagonistic.
B. Persons with rash and systemic symptoms from abacavir should never be rechallenged with abacavir.
C. ddC causes neuropathy.
D. ddI should be taken on a full stomach.
E. Macrocytosis can often be attributed to AZT.

22. Which of the following statements is false regarding the nonnucleoside reverse transcriptase inhibitors (NNRTIs)?

A. NNRTIs should never be given as monotherapy.
B. NNRTIs should never be given with one another.
C. Efavirenz can give patients a disconnected feeling.
D. Nevirapine increases some protease inhibitor levels.
E. Delavirdine increases some protease inhibitor levels.

23. Which of the following statements is false regarding treatment with protease inhibitors?

A. A major side effect of indinavir is kidney stones.
B. Ritonavir should be prescribed by dose escalation.
C. Drug resistance develops slowly with pt. nonadherence.
D. Problems with fat metabolism complicate treatment.
E. Protease inhibitors with cisapride is contraindicated.

24. Which of the following general principles regarding anti-retroviral treatment for HIV infection is false?

A. Effectiveness of anti-retroviral therapy should be based on plasma HIV RNA levels.
B. Consider changing antiretroviral therapy if plasma HIV

RNA is not undetectable after 6 months of treatment.
C. HIV RNA should be measured before and one month after each change in anti-retroviral therapy.
D. Prophylaxis for opportunistic infections should be based on the CD4+ T-cell count
E. If the CD4+ T-cell count increases, prophylaxis for opportunistic infections can always be stopped.

25. Which of the following statements is false regarding the initiation of prophylaxis for opportunistic infections?

A. PCP prophylaxis should routinely be initiated when the CD4+ T-cell count is <200/mm^3.
B. Toxoplasmosis prophylaxis should routinely be initiated when the CD4+ T-cell count is < 100 cells/mm^3 if the inmate has a positive toxoplasmosis IgG.
C. MAC prophylaxis should routinely be initiated when the CD4+ T-cell count is <50/mm^3.
D. Fungal prophylaxis should routinely be initiated when the CD4+ T-cell count is <50/mm^3.
E. CMV prophylaxis is not routinely indicated.

26. Which of the following statements is false regarding the management of opportunistic infections for BOP inmates with HIV infection?

A. The prophylactic agent of choice for MAC infection is azithromycin 1200 mg given once weekly by directly observed therapy.
B. Before initiating MAC prophylaxis blood cultures should be obtained to screen for disseminated MAC infection.
C. The prophylactic agent of choice for PCP is trimethoprim-sulfamethoxazole.
D. TMP-SMZ prevents both PCP and toxoplasmosis.
E. Aerosolized pentamidine prevents PCP and toxoplasmosis.

27. Which of the following statements is false regarding the treatment of STDs?

A. Gonorrhea and chlamydia (urethritis) can be treated with oral ciprofloxacin 500 mg + azithromycin 1 gram.
B. Gonorrhea, chlamydia, and syphilis should always be treated by administering all doses of medication under direct observation.
C. Topical acyclovir is an ineffective treatment for genital herpes.
D. Bacterial vaginosis is associated with adverse outcomes in pregnant women.
E. Treating genital warts prevents the spread of HPV.

28. Which of the following statements about syphilis is false?

A. To diagnose syphilis a +RPR must be confirmed by a +FTA.
B. HIV-infected persons are usually treated with the same drug regimens as persons without HIV infection.
C. An RPR titer of 1:256 in an inmate with syphilis of unknown duration, that remains positive at 1:8, 12 months after treatment indicates treatment failure.
D. An inmate appropriately treated for secondary syphilis with an RPR titer of 1:32, that remains positive at 1:16, 6 months after treatment should have a lumbar puncture to screen for neurosyphilis.
E. A pregnant woman with primary syphilis who is allergic to penicillin, must be desensitized.

29. Which of the following is NOT a high risk condition for endocarditis following certain procedures?

A. Tetrology of Fallot
B. Prosthetic aortic valve
C. Prosthetic mitral valve
D. History of previous bacterial endocarditis
E. History of coronary artery bypass graft

30. Which of the following procedures requires prophylaxis for endocarditis in an inmate with a prosthetic aortic valve?

A. Cesarean section
B. Angioplasty
C. Intubation
D. Tonsillectomy
E. Pacemaker placement

31. Which of the following statements is false regarding varicella zoster viral (VZV)infections?

A. VZV is the cause of chicken pox and shingles.
B. A person can get chicken pox from another person with herpes zoster/shingles.
C. A person with chicken pox is contagious 1-2 days before the rash develops.
D. A self-report of a history of chicken pox is not reliable.
E. Complications of chicken pox can be severe, particularly in adults.

32. Which of the following statements is false regarding the containment of VZV?

A. Inmates with herpes zoster/shingles do not require

isolation from other inmates.

B. Inmates who are pregnant or have AIDS susceptible to chicken pox who are in contact with another inmate with chicken pox may be candidates for immunoprophylaxis.
C. Prophylaxis with varicella zoster immunoglobulin should be given within 96 hours of exposure to ensure efficacy.
D. Inmates susceptible to chicken pox should be considered potentially contagious 10-21 days after exposure to varicella.
E. Varicella vaccine is not indicated for susceptible contacts in contact with other inmates with chicken pox.

Infectious Disease Treatment Protocol Study Guide - Answers

Question #1 - Answer is B

Acute hepatitis A is confirmed by a positive HAV IgM titer that is present during the onset of clinical symptoms. Acute hepatitis B is confirmed by a positive IgM antibody to HBV core antigen (anti-HBc IgM) that develops concurrently with symptoms. The measurement of HBsAg may be clinically helpful, but its presence does not differentiate from acute or chronic HBV infection. Acute hepatitis C is diagnosed by eliminating other causes of viral hepatitis and documenting the presence of anti-HCV antibodies that are present in 60% of patients at the onset of symptoms.

Question #2 - Answer is E

The diagnosis of acute hepatitis A is critical in the correctional setting since large scale outbreaks of infection can occur, particularly if the index case is a food handler.

Infected individuals are contagious from three weeks prior to the onset of jaundice until 10 days after the onset of jaundice. Diarrhea markedly increases contagion. Cell mates, sexual contacts and other very close contacts of an infectious case should be administered immunoglobulin in accordance with CDC guidelines. Immunoglobulin prophylaxis must be administered within 2 weeks of exposure to be effective. Hepatitis A vaccine does not have proven efficacy for preventing infection in previously unvaccinated persons exposed to HAV.

Question #3 - Answer is C

By definition chronic HBV carriers are HBsAg+ and are considered contagious. Contagiousness is markedly increased with the presence of HBe antigen. Loss of HBe antigen occurring annually at a rate of 5-10%, indicates reduced contagiousness and predicts clinical improvement from chronic hepatitis. Loss of HBsAg occurs annually at a rate of 1-2% and usually indicates clearance of HBV infection and the development of immunity (anti-HBs+). The risk of cirrhosis and cancer increases with the duration of infection.

Question #4 - Answer is B

Persons infected with HBV are candidates for interferon alpha treatment only if they are HBsAg+, HBe+ and HBV DNA+ with elevated liver transaminases over a 12 month period. Chronic HBV carriers that are HBe- with antibodies to HBe (anti-HBe+) either have resolving hepatitis or an atypical form of hepatitis that will not respond to interferon treatment. Chronic HBV carriers that have normal liver transaminases have immunotolerance to HBV with minimal liver inflammation and respond poorly to interferon. The presence of HBV DNA should be confirmed prior to treatment, to ensure the presence of ongoing active infection since spontaneous clearance of HBV infection occurs. Fibrosis on liver biopsy correlates with a positive response to interferon treatment for HBV infection.

Question #5 - Answer is B

Among high risk inmates with abnormal liver transaminases, HCV infection can be adequately diagnosed by measuring anti-HCV by EIA. Inmates without known risk factors for HCV infection or normal liver transaminases should have their diagnosis confirmed by measuring anti-HCV by RIBA. The presence of HCV RNA should always be confirmed through a qualitative assay prior to initiating drug therapy for hepatitis C. Acute HCV infection is difficult to diagnose but in 60% of cases anti-HCV by EIA will be measurable at the onset of symptoms and is associated with rising ALT. Many different quasi-species of HCV have been identified. Reinfection with HCV can occur and exacerbate underlying disease. (e.g. ongoing drug use). Anti-HCV does not convey immunity.

Question #6 - Answer is D

Persons with chronic hepatitis C and normal liver transaminases are not candidates for interferon alpha treatment, since a beneficial response to treatment is unproven. A mental health evaluation is indicated prior to initiating interferon, since depression and other psychiatric problems are potential adverse reactions. A baseline liver biopsy is important to diagnose other etiologies of liver disease and to assess the severity of inflammation and fibrosis. The prescription of interferon for persons with liver failure and hepatitis C infection is absolutely contraindicated. Hepatitis B co-infection seriously complicates drug treatment for HCV infection, since the responses to therapy are managed differently for the two infections.

Question #7 - Answer is D

Ribavirin has no efficacy alone for the treatment of HCV infection. Hypothyroidism is a potential adverse consequence of interferon treatment and is frequently irreversible. A drop in hematocrit from hemolysis develops in 10% or more of persons treated with ribavirin usually within weeks of initiating therapy. Interferon and ribavirin in combination has efficacy for treating persons never previously treated for HCV infection and persons who were previously treated with interferon, responded and then relapsed, but is not effective in treating persons who have had no initial benefit from interferon therapy. Ribavirin is absolutely contraindicated during pregnancy due to the potential for birth defects and fetal death.

Question #8 - Answer is A

Routine screening for immunity to HBV is not indicated for staff prior to initiating the hepatitis B vaccine series. Staff who are known responders to hepatitis B vaccine (anti-HBs $\geq$ 10 milli-international units) do not require post-exposure prophylaxis for HBV following an exposure, since they are adequately protected. Routine booster doses of hepatitis B vaccine are not indicated for staff, since long term protection is usually provided with initial vaccination. Staff with percutaneous exposures to HCV should be monitored for symptoms of hepatitis and screened for HCV antibodies by EIA and liver transaminase abnormalities at the time of exposure and in 6 months. The mean incubation of HCV infection is 50 days. Approximately 60% of infected persons will have measurable anti-HCV at the onset of symptoms. There is no effective prophylaxis for HCV exposures.

Question #9 - Answer is D

All tuberculin skin testing should be performed using the Mantoux method by injecting 0.1 ml of intermediate strength PPD solution intradermally into the volar surface of the forearm. Tests are

measured in millimeters of induration and should be read 48-72 hours after administering the test. A positive test can be read up to one week after administering the test. A negative test read more than 72 hours after administering the test is considered invalid. Pregnant women can receive tuberculin skin testing without complications.

Question #10 - Answer is E

A 5 mm. PPD is considered positive for immunocompromised persons, for close contacts of active TB cases, and for persons with inactive old TB by chest radiograph. A 10 mm. PPD is considered a positive reaction for correctional staff and inmates. Inmates previously vaccinated with BCG should have their TB skin tests interpreted the same as unvaccinated individuals. Inmates who self-report a positive tuberculin skin test, without documentation, should be retested in order to document a baseline PPD in millimeters, unless they report a severe reaction to previous testing. Establishing an accurate PPD reading is an important for treatment and infection control purposes. Severe skin reactions are rare.

Question #11 and #12- Answers are A and E

The indications for TB chemoprophylaxis are based on the likelihood of TB infection, the risk for developing TB disease, and the risk of hepatotoxicity. For healthy inmates at intake without concurrent illnesses, preventive treatment should be offered to inmates under age 35 with a PPD of 10 mm. or more. Healthy inmates at intake without concurrent illnesses who are 35 years of age or older with a boosted or unboosted PPD of 10 mm. or greater should not be prescribed isoniazid since the risk of hepatotoxicity outweighs the risk of TB disease from old latent TB infection. A boosted tuberculin skin test indicates old latent TB infection.

Inmates with HIV infection or severe immunosuppression or close contact to an active TB case who have a PPD of 5 mm. or greater should be considered for chemoprophylaxis regardless of age. Inmates with a PPD of 10 mm. or greater, with diabetes, dialysis-dependent renal failure, gastrectomy, silicosis, head and neck cancer, hematologic malignancies, or history of injection drug usage should be considered for preventive therapy regardless of age.

Healthy inmates evaluated for TB infection during annual screening should be considered for TB chemoprophylaxis with an increase in their PPD skin test within the past 24 months of 10 mm. if < 35 years of age and of 15 mm. if 35 years of age or older. Note: Any inmate with an increase in their PPD reading to greater than 5 mm. during annual screening should be evaluated on a case by case basis by a clinician, since a lower threshold

for prophylaxis may be warranted if the person has concurrent illnesses such as HIV infection or evidence of close contact with an active TB case.

Question #13 - Answer is C

The risk of isoniazid hepatotoxicity increases with age, evidence of underlying liver disease, pregnancy, and among African-American and Hispanic women. INH hepatotoxicity can occur anytime during treatment, but most commonly occurs within 4-8 weeks of initiating therapy. All inmates should have baseline hepatic transaminase levels assayed before initiating treatment. Inmates at high risk for hepatotoxicity or with baselines elevations should have monthly transaminase assays. All inmates should have a monthly symptom review for side effects to INH. Inmates with AST or ALT 3-5 times normal should generally not be started on INH, unless the risk for TB is very high and an expert physician consultant has reviewed the case.

Question #14 - Answer is A

Persons with HIV infection who are contacts of an active TB case are at high risk for developing TB (approximately 10% per year once infected). HIV-infected inmate contacts should be evaluated on a case by case basis to determine if TB chemoprophylaxis is indicated. In this case, the risk of TB infection was extraordinarily high and the inmate contact was markedly immunocompromised, making PPD testing unreliable. Anergy testing is poorly standardized and of uncertain predictive value. PPD testing should be conducted on all HIV-infected contacts since they may have measurable reactions, despite immunosuppression. In this high risk case, chemoprophylaxis is indicated even with a PPD result of 0 mm.

Question #15 - Answer is E

Active non-resistant TB should always be treated in accordance with BOP protocols adapted from CDC guidelines unless medical contraindications to the recommended regimen are identified. Initial treatment with four drugs for two months for cases of suspected or confirmed TB is recommended to reduce the emergence of resistant disease and to reduce contagion. Active TB should never be treated with a single agent. At least two new drugs should always be added to a failing TB regimen. Pulmonary and extra-pulmonary TB are generally treated with the same regimen, although extended therapy may be required with TB meningitis, lymphadenitis, and osteomyelitis. Multi-drug resistant TB should be treated in consultation with a TB expert, often for 24 months.

Question #16 - Answer is E

Persons with non-resistant pulmonary TB rapidly become non-

contagious within two weeks of therapy when placed on a four drug TB regimen as recommended by the CDC. Inmates should remain in AFB isolation until they are clinically improving, on two weeks of four drug treatment, and have three consecutive negative AFB smears of the sputum. Persons who remain smear-positive or clinically unimproved should remain in isolation since multi-drug resistance is more likely. If multi-drug resistance is suspected based on history or clinical course, the inmate should remain in isolation until culture sensitivities confirm non-resistant TB. Confirmed multi-drug resistant cases of TB should be managed in isolation on a case by case basis, usually until three consecutive negative cultures are obtained, and the inmate is clinically improving.

Question #17 - Answer is A

Active TB should always be monitored by monthly sputum smears and cultures. Susceptible TB should respond to appropriate treatment within two months of initiating therapy, confirmed by negative sputum cultures. Persons with persistently positive sputum cultures require further evaluation. The standard four drug TB regimen should be prescribed as daily or twice weekly doses in accordance with BOP guidelines. Doses should not be split to reduce side effects, since drug effectiveness may be compromised. A common, usually clinically insignificant side effect of pyrazinamide is hyperuricemia. Pregnant women should not be prescribed streptomycin or pyrazinamide. HIV-infected persons taking protease inhibitors require a nonstandard treatment regimen, since rifampin is contraindicated. Persons with TB and HIV co-infection may require an extended course of drug therapy particularly with concurrent illnesses that may impact on drug effectiveness such as diarrhea. If malabsorption is suspected, drug levels should be measured.

Question #18 - Answer is B

The 1993 CDC classification system for the staging of HIV infection is based on CD4+ T-cell count or percentage (Categories 1, 2, and 3) and clinical symptoms (Categories A, B, and C). For classification purposes, the lowest accurate CD4+ T-cell count or percentage should be utilized. For classification purposes, Category B conditions take precedence over those in Category A; and Category C AIDS conditions take precedence over those in Category B.

Question #19 - Answer is E

Plasma HIV RNA testing is indicated for all persons with HIV infection since even asymptomatic persons with normal CD4+ T-cell counts may be at high risk for disease progression. HIV RNA can return to pretreatment levels within days of stopping anti-retroviral medications and is markedly affected by concurrent

illnesses and recent immunizations. HIV RNA should be measured before and one month after any changes in anti-retroviral therapy. A tenfold (1 log) change in viral load one month following initiation of an anti-retroviral treatment regimen predicts a viral load decline at 4-6 months to <500 copies or undetectable levels.

Question #20 - Answer is C

All inmates diagnosed with HIV infection should have a baseline CD4+ T-cell count, plasma HIV RNA testing, toxoplasmosis serology, chest radiograph and other indicated evaluations. Pneumovax immunization should be administered to all inmates with HIV infection with a booster after 5 years. Influenza immunization should be offered to all HIV-infected inmates annually each autumn. Anergy testing is poorly standardized with an unknown predictive value and is not routinely indicated for inmates with HIV infection.

Question #21 - Answer is D

A common side effect of AZT is macrocytosis that may or may not be associated with a severe anemia. Common causes of macrocytic anemia (e.g. B12 and folate deficiency) should always be investigated. The combination of AZT and d4T is antagonistic. Both ddI and the protease inhibitor, indinavir must be given on an empty stomach and never at the same time. Neuropathy is a common side effect of ddC and may ameliorate with dosage reduction of ddC to 20 mg BID. Abacavir, is usually well tolerated, but a hypersensitivity reaction characterized by rash and associated systemic symptoms. Stopping the drug following a hypersensitivity reaction and rechallenging can be life threatening.

Question #22 - Answer is D

The nonnucleoside reverse transcriptase inhibitors (NNRTIs) should never be given as monotherapy or in combination. Efavirenz, the most potent NNRTI, is associated with a disconnected feeling, that usually abates with treatment. Nevirapine decreases levels of some protease inhibitors; while delavirdine increases the levels of some protease inhibitors. Adjustments in protease inhibitor dosages when combined with NNRTIs may or may not be required depending on the specific combination.

Question #23 - Answer is C

Protease inhibitors are potent antiretroviral agents that must be taken strictly as prescribed to prevent the rapid development of drug resistance. Indinavir must be taken on an empty stomach with at least 1.5 liters of water per day to reduce the incidence

of nephrolithiasis, a common drug side effect. Drug interactions must be reviewed carefully when prescribing protease inhibitors. Protease inhibitors should never be prescribed with terfenadine, astemizole, or cisapride, since life threatening cardiotoxicity can result. Protease inhibitor use has been associated with abnormalities in lipid metabolism and lipodystrophy (redistribution of fat). The ritonavir daily dosage should be reached by dose escalation over two weeks to minimize drug side effects.

Questions #24 - Answer is E

Antiretroviral treatment should be prescribed based on current DHHS recommendations. The inmate's CD4+ T-cell count, plasma HIV RNA, previous treatment history, and drug tolerance are important in determining specific treatment regimens. Changes in therapy should be based on HIV RNA levels, measured before and after any changes in treatment regimens. Failure to achieve undetectable HIV RNA levels 6 months after initiating antiretroviral therapy is usually an indication for changing drug therapy. Prophylaxis of opportunistic infections is based on immune status (CD4+ T-cell count). If CD4+ T-cell counts increase after beginning a new antiretroviral regimen, prophylaxis for opportunistic infections should usually be continued, since the inmate's immune system may still be compromised.

Question #25 - Answer is D

Prophylaxis for opportunistic infections related to HIV infection is critical for reducing patient morbidity and mortality. Prophylaxis for PCP, toxoplasmosis (IgG+), and *Mycobacterium avium* complex (MAC) are routinely indicated based on CD4+ T-cell count. Oral gancyclovir is not routinely recommended for prevention of CMV systemic disease, due to concerns about the drug's effectiveness, toxicity, and cost. Prevention of fungal disease with fluconazole or other agent should be prescribed on a case by case basis. Routine prophylaxis with fluconazole has not decreased overall mortality and can result in significant drug resistance.

Question #26 - Answer is E

The prophylactic agent of choice for PCP is trimethoprim-sulfamethoxazole due to its superior effectiveness and its concurrent prevention of toxoplasmosis and many bacterial infections. The drug of choice for prevention of MAC infection among BOP inmates is azithromycin since the drug can be given weekly with limited toxicity and concurrently prevents many atypical bacterial infections. Screening for disseminated MAC by surveillance blood cultures prior to prophylaxis is recommended since disseminated disease requires a more complicated treatment regimen. Aerosolized pentamidine provides effective local

prophylaxis for PCP in the lungs, not systemic prophylaxis for other opportunistic infections.

Question #27 - Answer is E

All drug therapy for inmates with gonorrhea, syphilis, and chlamydia, should be administered in unit doses under direct observation. Ciprofloxacin (500 mg) and azithromycin (1 gram), both given orally in a one time dose, is the simplest drug regimen for treating the urethral infections of gonorrhea and chlamydia. Empiric treatment of chlamydia should always be included in treatment regimens for gonorrhea. Genital herpes should be treated with oral acyclovir. Topical acyclovir is ineffective. Bacterial vaginosis (BV) in pregnant women has been associated with premature labor in high risk women (those who have had premature deliveries in the past). Drug treatment of BV should be considered in consultation with an obstetrician. Human papilloma virus (HPV) is the cause of venereal warts. Treatment of warts does not necessarily eradicate HPV or prevent future transmission.

Question #28 - Answer is C

Syphilis is diagnosed by a positive nontreponemal test (e.g. RPR), confirmed by a treponemal test (e.g. FTA). Treatment regimens for syphilis in HIV infected persons are the same as those for HIV seronegative persons. Persons with HIV infection and syphilis, however, should be monitored more closely and should have a lower threshold for cerebrospinal fluid (CSF) evaluation for neurosyphilis. The only proven therapy for preventing congenital syphilis is penicillin; therefore pregnant women with syphilis and penicillin allergy must be desensitized. Therapeutic efficacy of drug therapy for syphilis should be monitored by serial RPR measurements. RPR titers should decline at least fourfold in 6 months for primary and secondary syphilis; and at least fourfold in 12-24 months for latent syphilis. Titers that increase, remain stable, or fail to decline by fourfold are an indication for CSF evaluation. RPR titers may decline gradually over many months to years and remain positive at a low level even with adequate therapy.

Question #29 - Answer is E

Question #30 - Answer is D

Question #31 - Answer is D

Varicella zoster virus (VZV) is the cause of chicken pox and herpes zoster or shingles. Persons with shingles can shed VZV to

others causing chicken pox in susceptible contacts. Persons with chicken pox are contagious 1-2 days before the onset of rash, until the rash crusts. A self-report of chicken pox is highly reliable, with an estimated 98% accuracy.

Question #32 - Answer is A

Inmates with chicken pox or shingles should be isolated from the inmate population to minimize the possibility of a varicella outbreak and the serious complications associated with adult-acquired chicken pox. Susceptible inmate contacts should be considered potentially contagious 10-21 days after exposure to the index case of chicken pox. Immunocompromised and pregnant contacts, susceptible to chicken pox based on a self-reported negative history, are candidates for varicella zoster immunoglobulin (VZIG) prophylaxis (that must be administered within 96 hours of exposure to have proven efficacy). Varicella vaccine does not have proven efficacy for post-exposure prophylaxis for chicken pox.